HIT Standards Committee
Final Transcript
April 20, 2011

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody. Could you please take your seats? Good morning. Welcome, everybody to the 24th meeting of the HIT Standards Committee. This is a Federal Advisory Committee, and there will be opportunity at the end of the meeting for the public to make comments. Just a reminder, too, for committee members to please identify yourselves when speaking. We are transcribing this conversation and it will be available on the ONC Web site.

Let's begin with introductions around the table, beginning on my left with Steve Posnack.

Steve Posnack – ONC – Policy Analyst
Steve Posnack, ONC.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Doug Fridsma, ONC.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Walter Suarez with Kaiser Permanente; member of the committee, and no conflict.

Judy Murphy – Aurora Health Care – Vice President of Applications
Judy Murphy from Aurora HealthCare.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
David McCallie, Cerner.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Dixie Baker, Science Applications International.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Jon Perlin, HCA, ... Vanderbilt University.

Farzad Mostashari – ONC – National Coordinator
Farzad Mostashari, ONC.

John Halamka – Harvard Medical School – Chief Information Officer
John Halamka, Harvard Medical School, Beth Israel Deaconess Medical Center.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Jamie Ferguson, Kaiser Permanente.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Carol Diamond, Markle.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Stan Huff with Intermountain Healthcare and the University of Utah.

B.J. (Bettijoyce) Lide – NIST – Scientific Advisor for HIT
B.J. Lide, NIST.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
John Derr, Golden Living.

John Klimek – NCPDP – VP Industry Information Technology
John Klimek, NCPDP.

Judy Sparrow – Office of the National Coordinator – Executive Director
We do have a number of members on the telephone. Cris Ross, are you there?

Cris Ross – LabHub – CIO
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Wes Rishel?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Jim Walker? Kevin Hutchinson?

Kevin Hutchinson – Prematics, Inc. – CEO
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Liz Johnson?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Chris Chute is also here in the room. Sharon Terry? Nancy Orvis? Janet Corrigan? And Martin Harris?

Martin Harris – Cleveland Clinic – Chief Information Officer
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Did I leave anybody off?

Anne Castro – Blue Cross Blue Shield South Carolina – Chief Design Architect
Anne Castro.

Marc Overhage – Regenstrief – Director
Marc Overhage is on the phone.

Judy Sparrow – Office of the National Coordinator – Executive Director
With that, I'll turn it over to Dr. Mostashari.

Elizabeth Holland – CMS – Director, HIT Initiatives Group, Office E-Health Standards & Services
Elizabeth Holland is on the phone for Karen Trudel.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you!

Farzad Mostashari – ONC – National Coordinator
Steve Ondra just joined us as well. Good morning, everybody. I'll be brief. This is going to be a fun summer. Doug Fridsma has labeled this "The Summer of Fun," in fact, as we will hear more from Doug about the process and the timelines for taking the recommendations from the Policy Committee and translating those into the deliverables that this committee is responsible for, including the certification criteria proposed as well as standards. Boy, there's a lot of really, really fun stuff that is coming up. I think this balance between the Policy Committee and the Standards Committee and the important role that we have for these committees to be the point of connection to the outside community bringing those perspectives from the field and also to help bring us, ONC, and our federal partners together with the community has been just a wonderful model.

In fact, some of our, I think we heard last week at the Policy Committee hearing that some of our federal colleagues are covetous of the FACA process that we have established and are asking us how did you do it, how do you run it, how do you get such great work accomplished in partnership with your FACAs. So we tend to say, "Her name is Judy Sparrow." [Applause] I'll pass it over to John to review the agenda, but I just want to, again, give a hearty thank you for all the work you do and my appreciation. Oh, I did also want to tease the gentleman to my left for being, I guess one of now 12 full Harvard professors under the age of 50, John Halamka.

John Halamka – Harvard Medical School – Chief Information Officer
More importantly, I attested to meaningful use this week.

Jonathan Perlin – Hospital Corporation of America – CMO & President
So John, you've got full professorship at Harvard with tenure and so let's hope it's attestation with tenure for everyone as well. Good morning, everybody, and thanks very much, Dr. Mostashari for your leadership and everybody who has been a part of this process, and so we look out here from the FACA, for those who follow online there are quite a number of people here. Indeed as someone who's spent much of, if not most of his career in the federal government, I would concur, Farzad, with your assessment. This has been a terrific process because of the ONC staff, because of a robust committee, but most importantly because of the robust participation and input—sometimes in person, but quite copiously, as Judy would also attest, through all the mechanisms of review.

That's necessary for something that's as sweeping as these activities, and perhaps never more so than the current moment. It's really quite remarkable when Judy identified, and this is our 24th meeting, to look back and think about how much has occurred in that period of time. As we look across the environment, just as John Halamka indicated, we've moved from really colleagues developing a conceptual framework to yesterday, or this week, the first attestation that John Halamka, at 8:01, for the record, a minute after the site opened—

M
....

Jonathan Perlin – Hospital Corporation of America – CMO & President
A little longer, okay, a minute and 30 seconds. But promptly after that to really a process that really is the legacy of those early activities. That's terrific. So we moved the train out of the station but there's a track and the goal remains the higher value, more effective, safer, more efficient healthcare that all of us aspire to. That's really the image. But we have these intermediate processes and we're at this critical juncture in terms of their relationship with the process ... requirements of meaningful use. Today I think the agenda is really such an important one because it brings the number of threads together that intersect from past activities and really help to provide clarity in the go forward for the next sequence of activities for meaningful use stage two and three.

It does that specifically. It integrates activity and recommendation insight from PCAST, and I want to commend John for really holding us to task collectively. Last time he said, look, we've got a lot of activity coming together in terms of the stage two requirements. We need to make sure that we can not only achieve all of those activities, but make sure that we elicit the public comment, the input and the

preparation. So that all of the threads of responding to the requirements for standards, implementation guidance, certification criteria for the forthcoming stage two are really paced over the next few months of activity and in a way that we're holding ourselves accountable and open in terms of that sequence of events.

That's by way of introduction to what Doug Fridsma will really be talking about in terms of the relationships of those sets of activities to the calendar and to the S&I framework. I think it will help us bucket our activity, those things for which standards are fairly clear, and we, with public input and the insight of the broadest perspectives represented around this table, are able to identify that's in pretty good shape there. Those areas that are close ... and we can close the loop rather rapidly. Those areas where we've got challenges, where there's work that needs to be done in terms of standards development, and that will happen on a nice flow.

This is really a terrific sequence today. I'm very appreciative to have this morning Paul Tang to bring us up to date on the stage two discussion recommendations from the Policy Committee. Our intersecting, in terms of our thoughts about the charge of our committee, the standards, the implementation guidance, the certification process and criteria, the incorporation of the guidance, the hard work of the PCAST Workgroup in terms of helping to understand and make actionable the aspirations of that terrific work. Then really getting down to a lot of the foundational activity that supports, of course, the Clinical Workgroup and Privacy and Standards, and the terrific activity that's gone on in both, that are really prerequisites for getting to the level of the standard, getting to the level of the policy, and getting to the level of support for the better attributes of improved healthcare ....

So there's a construction of the vision, a reconciliation with history and what exists. Then really threading the needle to provide very concrete and specific recommendations for not only ONC, the review process to work with, but also to help those in the different sectors of the information ecosystem to really understand what's coming and to how collectively we get to this new place. So I think it's pretty exciting. We've been at it for 24 meetings but I sense a continuing, if not strengthened enthusiasm because it's no longer theoretical, it's getting very, very real. I want to thank everybody, Farzad and your team, Doug, Judy, all the folks who behind the scenes have been keeping this going even when we get to go back to our day jobs.

Along those lines—once again, an incredibly sensitive and thoughtful portrayal of the discussions at the last meeting. Are there any amendments or corrections that anyone would like to offer on the minutes? Hearing none, we'll declare consensus on those, but before we move into the agenda proper I'd like to turn to my terrific colleague and now full professor at Harvard University, John Halamka. Good morning, John, and congratulations.

John Halamka – Harvard Medical School – Chief Information Officer

You guys are embarrassing me here. I was meeting with a business leader yesterday and he said, how do you build a high performing organization? This analogy is not precisely perfect, but he said, you take race horses and you give them a track to run on and you make sure that the track is actually dirt, not ice or something that they'll slide on. When I look at the work that Doug has done and actually the work of this meeting, and all of you are thoroughbreds in your field and we need to make sure we know where we're running and that the track ahead is clear. So there are a couple of things we need.

Dixie and I have had many discussions, if we have a Policy Committee that has a set of policy goals and we have a Standards Committee and we have an S&I framework, what exactly is it that we do to support that process? Well, the answer today is going to be made very clear, that as we are given a policy imperative, are there standards needed to support it? If so, is there one obvious standard that we can just pick? No one would argue with it. We're going to traverse the Web. How about HTTP and HTML? Oh, that sounds good. Are there standards that exist, but they're just not exactly right. They're close.

One of the frustrations that I had in the HITSP activity, was that we're not an SDO, right, so we had no choice but to simply lift off the shelf things that were already done whether they were perfect or not. There was no opportunity to polish. There was purely opportunity in implementation guide to describe the

implementation detail. Here, as we'll hear from Doug, actually there is a process of the S&I framework that if polish needs to be done it could be. Then there may very well be no standards, that is, we all have to get together and say hey, it's a whole new world driven by the Web and the only standards that exist were pre-Web and we'd better actually ... something from scratch. So by saying we will have a process laid out of work, guided by meaningful use stage two with very specific topics every meeting and a set of choices, perfect standard, standard with polish, no standards exist, we will know exactly what to do. So I think it's going to be a fun summer, as you said. I do look forward to Paul's remarks, and hopefully we'll get some specifics on meaningful use stage two to guide us and then we will take off and do the work.

I want to also comment, and that is much of the work ahead is going to be clinical, so Jamie's all going to do it himself. It's going to be great. Obviously, we recognize that we have a large team of talented people that need to be engaged in all of the work ahead. Of course, Jamie, yes, you will be given a huge amount of activity, but I think also what we'll hear from both Farzad and from Doug, is that probably we're going to need to create ad hoc power teams. If we are given, as you'll see, 26 issues to work on maybe oh, we create—I'll make up something—the power team on patient matching. That power team then comes together, figures out what existing standards or policies the procedures have existed for patient matching, comes up with a recommendation, and then just .... It's the only way we're going to get through 5 months of 26 different tasks is by creating these. Yes, we have our existing workgroups, but power teams to supplement those. So if we've got the plan and we've got the deliverables clear and the people to do it, it will be a great .... So I look forward to the agenda and kicking off the process.

Farzad Mostashari – ONC – National Coordinator

Before we go to Paul and Josh, I just want to reprise part of the discussion that we had last week at the Policy Committee that I thought was pretty important and pretty terrific. That was the recognition of what is happening outside of meaningful use and certification criteria and standards and the recognition that the work we do can benefit from and can benefit in turn in a virtuous cycle the other changes that are happening out there. Changes like the National Quality Strategy, where we actually have now a set of priorities and a framework, which, good for us, looks a lot like the framework we've already been operating under in terms of the meaningful use framework. But it highlights some very specific goals, for example, around patient safety. In fact last week there was the launch of the Partnership for Patients, which now has over 1,000 organizations, hospitals and others, who pledged to be a part of the Partnership for Patients to reduce hospital readmissions by 20% and to reduce in-hospital adverse events by 40%. It's a fantastic opportunity for us to bind what we do to those larger health and healthcare improvement goals and for us to take another look at what our priorities have been and make sure that they are in alignment with the broader priorities of the nation.

There's also the payment, the real transformation in how nearly everybody thinks payment is going to be no longer dependent simply on the quantity of services delivered but on measures of seamlessness, the coordination of care, the quality of care, the safety of care, and yes, the efficiency of care delivered. Again, if this becomes, as Neil Calman put it succinctly, "If this becomes a choice between," and I'll put this in quotes, "ACO," because it's not just the reg that was released. It's the whole body of new types of payment models, whether it's bundled payment, shared savings, ACOs, medical home and so forth, but If it becomes a choice between ACO and meaningful use, ACO's going to eat meaningful use for lunch," is what Neil said. He's right, we can't have this be a false choice between do we implement electronic health records, or does our organization see what we have to do to succeed for delivering coordinated, high quality, safe and efficient care? These cannot be a choice. What we do has got to be in the service of those larger health and healthcare improvement goals.

I think it's an incredibly exciting time because for so long the technology has not been implemented, the standards have not been implemented, the exchange has not happened, because there wasn't a business case. Now, increasingly the business case is there and our role now is to accelerate and to help create more power, more strength, and shorter time frames in terms of being able to effectively implement those nationwide. So it's an exciting time and I'm just really proud of our ability as a community to be able to make a positive impact in those larger changes. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks, Farzad. I think that's a terrific introduction to the next discussion on stage two. To go back to our first work together and the first comments from ONC after HITECH was launched, you remember the arrows, and Paul, for those of us who worked in the quality arena through structure, laying the foundation, the process and the outcomes, accountable care really is a demand for the outcomes. What's so exciting about stage two is whatever our beliefs about the organizational forum of accountable care, I think the world is different and it demands accountable care. I, for one, don't know how to get there without information systems to support that kind of care with the sorts of attributes that Farzad just mentioned, safe, effective, efficient, indeed even compassionate because the information ....

M
....

Jonathan Perlin – Hospital Corporation of America – CMO & President
Patient-centered, exactly. What's so exciting to me about stage two is that we're making that segue from the foundation for those sorts of supports to begin to answer the sorts of questions or demands that accountable care, in all of its forms, requires. So that's terrifically exciting. In other words, we're getting to the really good stuff. I like that. And it's going to demand a great deal of folks, Dr. Halamka and Dr. Mostashari have outlined, in terms of the work ahead to support that good stuff with the right stuff in terms of standards. So this is a moment of intersection and calibration and a pleasure to introduce Paul Tang, who I believe joins us by phone, and Josh Seidman, to bring us up to date, a high level report from the recent activities of the Policy Committee. So we welcome Josh here in person and Paul, I believe, on the telephone.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you, Jon. Can you hear me?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Yes, Paul, we can hear you. If you can speak just a little louder, that would be perfect.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
All right, I'll try to do that. I really appreciate the opportunity to update the Standards Committee. This has been a wonderful kickoff to this meeting, and I agree with all the statements about that this is really a moment in time and it's a long march to a better system, one that's better quality, affordable and using techniques for delivering proven care. Interestingly enough, HITECH actually had all that in mind even before the Affordable Care Act, and I think we're building on the good charge that was given to us.

So can we advance the slide, please, and first is to acknowledge the dedicated work by a group of individuals who fearlessly and relentlessly tried to shoot toward the objectives that were mentioned before. We want to give people the tools, if not the ... itself, but give people the tools to achieve better care more affordably and achieving higher health outcomes in the end. These are the folks that have been with us for a very long time over the two years and continue to work with those goals in sight.

In this presentation, we want to update you on what we presented to the Policy Committee and where we are at this point in time, so I'm going to give you a high level summary of some of the comments. We had a Request for Comment go out and had a large response and wanted to summarize that for you. And talk in particular about the timing concerns that came back to the comments and give you some options and be open to your discussion, and in the context of that wanted to review the statutory constraints that are built into the HITECH provision.

To remind you of our work plan, once the finish rules were issued in 2010 we began working on stage two. And over the past several months have had hearings to fill out some of our knowledge base and the public's input on a number of topics, which include specialists and follow up practices in hospitals, state issues, particularly in Medicaid, ways that meaningful use can be applied to health measure and reduce healthcare disparities. We had separate hearings on patient and family engagement, population public health and care coordination, and you'll recognize that many of these fit the five categories of meaningful use.

In December, we presented the initial stage two draft criteria concept to both the Policy Committee and I believe we also presented to you back then, and then with their feedback went out with a Request for Comment that came back by February the 25th. The wonderful staff at ONC summarized those comments over the subsequent month and towards the end of March gave us an overview of those comments. Since that time, and through this month and part of next month, the Meaningful Use Workgroup is working on reconciling the input we received. As well as the input from other workgroups, both within the Policy Committee and the Standards Committee, to put it to finalize our initial draft recommendations that we intend to present to the Policy Committee on May 11th. Now, for scheduling reasons we weren't able to get a second specialist hearing until May 13th, but rest assured we will incorporate that feedback as well. Our goal then is to have final, as we did two years ago, final stage two recommendations from the HIT Policy Committee for approval at its June 8th meeting. Next slide, please.

The comments from the RFC: There were 422 comments and largely they represented comments that were compiled by professional organizations, or at least larger organizations that polled their members and tried to get a consolidated viewpoint and submitted that to ONC. Very, very thoughtful comments, as Farzad mentioned, basically this wonderful collaboration with the public and the private sector and all the associations and organizations in the private sector to help make this as good as we can and to serve the needs of healthcare and health reform. Largely, the public felt that, one, a really round endorsement for the meaningful use program in the sense of how it was structured, the kinds of categories that support better health, and that's the real meaning of using these HIT tools, so, again, an endorsement of that program that was really set out in HITECH.

The folks generally supported the existing objectives. There was strong support for a number of new objectives we introduced in our initial stage two concepts, such as in addition to having electronic prescribing for outpatient medications. Adding discharge prescriptions from the hospital as one of those things that we'd like to see go electronically, with the addition of progress notes, use of electronic medication administration record, patient provider secure messaging, and recording patient preferences for communications. These are all new things that we introduced in stage two building towards that goal, the goal of improved partnership with patients and improved outcomes, so a good endorsement of those new objectives.

There was some mixed support for some of the other new objectives, such as advanced directives for eligible providers, that's moving from menu to core, at least that's the proposal, moving from menu to core, but also include the actual advanced directive, if it exists, have that in the EHR. The kind of mixed support actually raises some good concerns, in the sense, and this is the value of the public input, is we hear about things that we may have overlooked and want to figure out how to reconcile. So, for example if we do include the advanced directive, well then how do we make sure that that's kept up to date? Well, we do have an approach, for example, to make sure that it's date and time stamped, ... for the individual leader, the provider looking at it, to say, hey, do I think this is really up to date, how recent is this, and what would I have to do to make sure that it's up to date?

But questions like those came through, or longitudinal care plans, people agree with that concept but is it well defined? The answer is no, not now, but can we come up with some minimum data sets. These are examples of things that we will take a crack at. We will also, if it continues to be in our recommendations, pass this on to you for your help in terms of well, how could we put together a standard for both care plans and the elements in a care plan, those kinds of things, this is where we're going to have to partner. So we had really good input from the public on these issues. Next slide, please.

As I said, probably the biggest concern that came back is really like the objectives, really like where we're headed, but can we move the industry this fast and make sure that we feed the objectives without causing inadvertent side effects or inadvertent harm. That's the real question that's put to us and that we're going to discuss in just a minute. NIH actually wrote us a letter saying to complement the information that's typically in the EHR we would love to have family history, not only family history but family history in a structured, usable, computable form, and that's obviously also a valuable request. Next slide, please.

Before we introduce some of the options that we're thinking about or the way we're thinking about timing, I thought it would be useful to review the statutory constraints that are built into the HITECH legislation. As you know, the Medicare incentives are front loaded, so the goal is 2014 is the stake in the ground the president put to say we'd really love to have all Americans' history in electronic form, in EHRs by 2014. Whether we can achieve 100% may be challenging, but that's the goal. As a result, the timeline is based around that goal. So you want to get people to move as quickly as possible and for that reason Congress front loaded the incentive so that the earlier you get in, the more financial incentive you would have. Now, recognize, I mean one of the ways I look at this is this is an additional incentive on top of your need to implement these systems in order to take better care of patients. So that's really the driver and this is the government's way of providing additional financial incentive or additional financial support for you doing this, doing something that you already have to do.

These are front loaded so that for eligible professionals if you come in 2011 or 2012 you get the max, and for hospitals you have an additional year, so 2011 to 2013. The incentives in the Medicare program decrease over time. Now, Medicaid you can still receive the full payment as long as you meet, the initial one is just to start putting in an EHR and then you have to keep up with meaningful use during the six qualifying years of payment. As long as you get six qualifying years of payment by 2021 you can get the full payment. There is no more incentives because of the goal of 2014 if you've become a meaningful user after 2014 for Medicare. Final payments for Medicare, 2016, for Medicaid in 2021, and once you start this on the Medicare side you must keep up with whatever the then current meaningful use criteria are. If you miss out then you miss that year's payment. There's no penalty on the Medicaid side. We think about three stages of meaningful use 2011, 2013, 2015, but the statute actually gives the secretary the ability to continue beyond the 2015 in using and applying or revising meaningful use criteria.

In summary, the incentive policy lever is front loaded and the Medicare penalties exist in perpetuity and on the EP side can be a penalty of as much as a 5% decrease from the total and then there's an offset in terms of the ... on the hospital side, but those go on in perpetuity. This is the kind of either the carrot or the stick that the industry's reacting to, and we have to balance the desire to maximize their incentive with our ability to write criteria that moves the market the most without leaving too many people behind. That's a challenge that we've had from day one and we continue to want to do that delicate balance. Next slide, please.

In order to address the timing concerns, and they're legitimate concerns, and I put before you the levers that we're trying to take advantage of, the workgroup came up with an approach for modifying the timing, making recommendations about options to deal with the timing concerns. First, I thought I would review for you what is the concern that people raise? First of all, not everybody's concerned. There was a good support for keeping the current timeline and moving to stage two in 2013 and so on and so forth, by the consumer purchasers, the health plans, disease management organizations, as examples. The folks who proposed, again, support the program, support the objectives of the program, but think they need a little bit more time to comply with that are the hospitals, the physicians, the EHR vendors, the folks who actually are in the midst of doing this work.

A consideration about timing issues, if we add new functionality then in sequence a certain set of steps has to be achieved. If there's new functionality for the vendor community, they have to take time to develop specifications according to the final rule, develop it, test it, QA it, and help their customers deploy it. All of these things have to precede the next step, which is the provider then has to take the new version of their software, implement it, customize it, and train their workforce to use it effectively. Things having to do with health information exchange—and we all appreciate that it's not a material concept in the industry right now, but there are things that have to happen before people start and feel comfortable with sharing data that ... time, like building trust. Like together working to develop common policies, particularly related to privacy, having standards, not only the standards in place but implemented in a way that's consistent so you can literally share information in an interoperable way.

Certainly this committee can appreciate this is calendar time we're talking about, and unfortunately some of this has to be done in sequence. As an example, in the new functionality in stage two or any stage, we

have the final rule having to come out, the vendor development, the provider implementation, the reporting period, which currently for stage two requires a year's reporting period. That means the time the clock starts clicking at the time you implement any functionality, and then it goes on for a duration that's specified in the rule. Then the provider would qualify for the meaningful use stage. If we're only changing, let's say, the threshold, so instead of 30% it goes to 50%, but the functionality already exists in the EHR, then you remove that initial vendor development time. So it goes from final rule to providers doing something different, moving the threshold involving more folks to the comment reporting period and then the qualification. Next slide, please.

We tried to figure out what was in the statute and what we believe that the flexibility that HHS can have in setting the rules for stage two. How can we provide the most relief without backing down on the journey we're on in terms of providing systems and tools for health systems to improve the care and health of their patients and populations? There are several options that we came up with and new ones were introduced in the Policy Committee. One is that we can keep it exactly the way it is, same timeline, same one year reporting period, and have a mix of new functionality and existing functionality with potentially different thresholds. Another way we can help alleviate some of the time pressure is to reduce the one year reporting period to, for example, a 90 day reporting period as exists for stage one. In a sense that gives providers an extra nine months before they actually have to start the clock ticking on the use of the new functionality. So that seems to be one of the most efficient ways of alleviating some of the time pressure.

A third is to say, well, look, it looks like it's really too fast and let's delay the start of stage two by, for example, one year, six months, five months, whatever it is, one year. But one of the implications of that is that the providers would essentially get up to their third year payment for meeting stage one expectations and stage one criteria. Another approach is to say, recognizing the implications of new functionality versus changing thresholds of existing functionality, critically divides stage two into 2A and 2B. So 2A, let's say you already have in-house the tools needed to do your job, we'll raise the ante in terms of the threshold it takes for you to qualify for ... earning the meaningful use incentive and we would also add new quality measures. Now, there's a little ... in the sense that the EHR vendors would have to qualify their EHRs to make sure they comply with new quality measures.

Stage 2B then are for those objectives that do require new EHR functionalities, which require potentially that development in certification time. There are other approaches. That's where we would be interested in your thoughts—other ways that we can address the legitimate timing concerns while continuing to push forward. One of the challenges we have is we originally said stage two is where we start to get some robust health information exchange. We very much want that to happen, but we are where we are in terms of is the field mature enough to get that going so that we don't leave some of ... I think Farzad used the term, we don't want to leave the smaller practice, the little guy behind as we move the whole industry forward. Those are the ways that we thought about, starting ways we thought about in terms of the time concerns. Final slide, please.

In general, we had very strong support for the direction we're headed in with stage two. We did not fully specify, like you would in a rule, the objectives in our draft RFC, so we have to go back in and do more clarification of some of those things, and there was significant concern about the time required for development and implementation of new functionality that we described and we have some approaches for your comment. We're working on the reconciliation of the comments and addressing the details, particularly of the new requirements, and expect to present a full set of draft recommendations at the May 11th HIT Policy Committee for feedback prior to the final recommendations on the June 8th meeting.

With that, Josh, do you want to add anything?

Josh Seidman – ONC

Just a couple of other notes. One is that on the incorporation, as we build toward future stages and we talk about the latter going up, for individual providers who come in later to the program, just a reminder that there is an individual ladder for them as well. If they come into the program, say, in 2013, they would come in at stage one, is the way the program is currently set up. I will also say that the meaningful use

team and the Standards and Certification team have been working very closely and so we have been able to provide to the Policy Committee and the Meaningful Use Workgroup some guidance around what some of the new functionalities are and whether they would require new standards and/or new certification criteria. So they've had that guidance and so that's something to consider. When Doug and Steve present later they will talk about some of the buckets of those different things that ....

The one thing that is not in there, I'll just note, is that, as Paul noted, there are other workgroups of the Policy Committee that are also developing recommendations. One of those is the Quality Measures Workgroup. One of the things that has been high on their priority, both on the patient and family engagement side and the care coordination side, is the potential incorporation of patient reported measures, and so that's another thing that the Meaningful Use Workgroup has not been discussing so much but would be something for consideration by this group as well. I think those were my additional notes.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Paul Tang and Josh Seidman. In fact, not only the Policy Committee but all of the workgroups working with the Policy Committee appreciate this great update. We certainly welcome comments and discussion. I am reminded that really the piece that we need to make sure that we're commenting on—so a lot of this may be emergent as we speak with Doug Fridsma or Doug talks to us about the relationship that John Halamka spoke of. Which is where standards are available we're going to need some where, if they were absent really standards development needs to be commissioned, given what we understand of the proposed stage two criteria, what can we offer back in terms of really parsing that level of availability of standards as the Policy Committee and ONC contemplates different permutations of timing. That is to say, it's really within the Policy Committee and ONC to contemplate the timing. I think all of us have been very sensitive to the issue of wanting to support the momentum in the context it's been offered before, that moves everybody to where the aspirations for meaningful use in support of healthcare ally at a speed that's as efficient as possible.

Now, to what extent are we a gate function in terms of the availability of standards? So the ... I'd like us to bring to this discussion is really in the context of standards availability. Then ... that we can determine fully at this juncture, and it may be informed to an even greater degree through the S&I framework and the interrelationship that Doug speaks about. Do you want to, Dr. Mostashari—?

Farzad Mostashari – ONC – National Coordinator
I think it's a great framing that Jon's offering in terms of what respective roles are. The one thing that we didn't do in the last go around that I wish we had was to have the Standards Committee consider the certification criteria as well as the standards, what are the objective tests that could be implemented? I think we really could have used your insights and help into that. I know that there's a heavy burden on this wagon, but I think it would be important to have at least a sense of going from the meaningful use requirements to what would be the test of that functionality within the electronic health record, and then what would be the standards that it would ....

Jonathan Perlin – Hospital Corporation of America – CMO & President
In your mind's eye I think all of us are beginning to get a sense of a matrix that has to be completed, including not only the presence of standards but the certification tests. That really becomes a constructive blend with which to comment both in support of the policy standards recommendations themselves and the meaningful use criteria, specifically as well as implications about the state of play, the state of possible standards, and the timing. Let me take two comments. Doug, you may want to jump in, and John Halamka as well I think has some insights.

John Halamka – Harvard Medical School – Chief Information Officer
Just one quick follow up to your statement, so, Dixie, would you have envisioned a certification criteria that required every provider in America to manually demonstrate SHA-1 and AES encryption and decryption? My guess is no. In fact, let's just imagine a different certification test that said NIST had a test bed and you needed to exchange a package of data with that test bed and the act of exchanging it would have demonstrated a successful implementation of a hashing or AES or Pitts' compliant algorithm.

That would have been great because as it was, having gone through the certification process, I had to show, okay, I type in "Hello World" and it's now turned into "AQ123F27." Isn't that exciting? I'm not sure it necessarily demonstrated interoperability and it was certainly painful, and in fact, no provider would actually have a piece of software that for real did that in the context of their clinical care. So I love the idea of having us participate in the development of certification criteria and the Implementation Workgroup has already been asked to be engaged, and especially working with this to make sure that those criteria are reasonable.

So, Paul, just a couple of follow ups for you. As we take the charge that Jon has described one of the things that we need is some functional characteristics of some of these, let's say, strong support objectives. When you say electronic clinical progress notes, I think that's a wonderful idea. What does it mean? Is that a scanned PDF of a piece of paper, because that is electronic, or is it native capture using a mobile device? Is it voice recognition which is electronic, so dependent upon the answers to those questions you conceivably could have different standards, or, similarly, what is an electronic medication administration record? Is that bedside medication verification with bar coding? What exactly is the workflow? Because again dependent upon what it is, there will be different standards. So what I'll hope, Paul, is are you working on functional descriptions of what some of these strongly supported new objectives might be?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
It's a good question, John, and also I appreciate the framework that Jon Perlin offered in terms of well, how can we help in terms of these standards. Some things come to mind just from the discussions already. For example, as you know, structured lab results as a menu option for stage one, the thought is to move that into core, that's the intent of the final rule anyway, and it's noted that LOINC, for example, is not a requirement. Could we tighten that up? These are things that probably there's already signals of areas where the HIT Standards Committee can already help us. Another comment that was made by more than one individual on the HIT Policy Committee and others is well, multiple standards ..., so take one. So offering choices does complicate the situation and makes it a little bit harder to be interoperable. A lot of the documents that are already in play, whether it's clinical summary or the longitudinal care plans, or even who's on my care team, which you might think that's really helpful to everybody, but how do you actually do that in an interoperable way. So you can see ... that there's a lot that we currently don't think of as already having standards but we need to start heading in that direction.

Another one thing that came up related to PCAST recommendations, they had a recommendation for stage two to apply some of their concepts, the metadata tagging, to the downloadable record that a patient can request out of an EHR. Well, if you take their structure, and already CCD, for example, is a structure that we've asked for the downloads to occur in, are there already standards for metadata to be applied to some of the sections of CCD? Now, to talk directly to some of your examples you raised, John, we've got the comments band the workgroup's already in agreement with the comments that, for example, scanned progress notes do not qualify. So, for example, the better modifier might be searchable progress notes, so, yes, transcribed notes would certainly apply and other ways that you can get searchable text from your progress notes. In the eMAR situation, for example, we went away from prescribing technologies such as bar coding and talked much more of an automated function between the capture of the CPOE medication order and how it gets recorded.

So we're doing some of that, and we'd be happy to receive questions like the ones you post to make sure that we go as far as we can go. But we will turn around probably and ask for standards recommendations on some of the ways that we make some of these things, both implementable in a consistent way, as well as have the standards to make the information truly interoperable.

M
Thanks very much. Just one last point on the list, care team members, I have heard such things as I know what we'll do is we'll mine every claim you've ever had and then automatically from those claims determine who your caregivers were to produce a longitudinal care team summary. Not that, Paul, you're suggesting this, but the industry is thinking these sorts of thoughts, and again, if that was the intent the

amount of infrastructure and standards to create such an HIE based auto ... care team presentation would be significant.

M
Right.

Jonathan Perlin – Hospital Corporation of America – CMO & President
This thread is terrific because it really highlights the challenge of specificity and intent. It takes me back to the adage of one of my favorite philosophers, Yogi Berra, who commented, "In theory, theory and practice are the same. In practice, they're not." This is a challenge in terms of the specificity. We know what we want, but what we're highlighting is not just the specificity of what we'd like to do in terms of the criteria, but the ambiguity that exists in something that you would think is straightforward conceptually as the care team or what electronic ... or any of those things. So we're going to have to really hold ourselves to be very exacting, but also sensitive to the realities of the environment so that we put something forward that is aspirational and appropriate in ... but also possible and pragmatic, practicable in operation.

I want to turn to Doug Fridsma for some training comments. We have a number of cards up, and electronically I know that Wes Rishel has comments and then following that we'll go around the table starting with Stan Huff, Carol Diamond, then to David McCallie and Walter Suarez. But let's start with Doug for some training comments following Paul and Josh's presentation.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Thank you. I have a couple of comments to make. But first I'm going to turn it over to my cardless counterpart here to just make a comment.

Steve Posnack – ONC – Policy Analyst
This is Steve Posnack. I think John Halamka noted kind of an important point that I think requires a little bit of additional clarity in terms of the distinction with respect to testing and the certification criteria. The certification criteria expressed capabilities that the EHR technology needs to include. How you test them most efficiently is really the process by which I think there could be a lot of optimization, so stringing together a sufficient test package for showing that hash encrypted message goes across in one fell swoop can be tested all in one shot, and I don't think there's necessarily anything preventing that from occurring today. I think for simplicity and the Herculean effort that NIST had to do to get their test methods out right away for EHR certification to take place necessitated individually focused test methods for each certification criteria. But going forward, I think that would be optimizing and getting feedback from you all about how to best optimize the testing method associated with those capabilities would be really helpful.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I make a distinction between performance testing. It's a little bit where you can do the thing that the certification criteria stipulates, and what, for lack of a better term, interoperability testing in which you string together those conformance tests into a conversation, so that you can say I can do A and B and C and I can complete a transaction. That's one of the things that we need to think about as we go from can I generate a transition of care document, to can I generate that, encrypt it, send it, acknowledge that it's been received, and complete that transaction. So I think that's going to be what we need to think about as we make the distinction between the certification criteria and the testing methods.

I think the other thing, and we'll talk a little bit more about this when we talk about summer camp, is that we've got a whole variety of different work that we need to do. I think that there is going to be tremendous value early in the process before the recommendations are finalized to make sure that we have that really tight coupling between the policy and technology. To make sure that what happens with the policy objectives can be well represented in the testing that we do into the certification criteria and the implementation guides and standards that we've got. So we've got some work, I think, to have that conversation and that dialogue. What I think we want to avoid is a waterfall methodology in which the policy objectives are thrown over the transom and then we're expected to try to figure out how to manage those. Because there are sometimes nuance changes that can be made early in the process that will get

it to a much better outcome with regard to our policy objectives by making sure that we have feedback from this committee early.

Jonathan Perlin – Hospital Corporation of America – CMO & President
This has been tremendously helpful and I think all of us appreciate the wisdom, and obviously very resonant with a lot of the sentiment I imagine you're going to have for extended discussion on that interaction during your session momentarily. So I want the group to rest assured that we'll come back to that, and there's a graphic ... I'm sure that actually is up in front of us that will get to some of that interplay. So we'll coming back to that. With that in mind, let's go to some of the other comments. Wes, I think you had your card up electronically?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes, thank you, Jon. I first have to ask now that John Halamka is a full professor at Harvard, has he taken to wearing a bow tie?

M
I'll leave that honor to the gentleman on my right.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay, the comments that I would like to make are a little bit varied. I'll just run through them all rather than interact. I would suggest that as we look at the means, both the qualification by certification and the means, we keep in mind the limits of certification. Someone commented already that we find that a given menu quality measure can be collected and that output can be generated. That does not necessarily create any feedback on whether a given institution will choose to collect that data through a structured dialogue with the physician or choose to infer it somehow. I'm afraid there's an awful lot of quality data for stage one that's being captured in the HIM department after discharge at this point. We, therefore, need to consider in the approach to the timing for meaningful use stage two that even things that are nominally just using an existing table driven capability to capture a new data element and report it may require more implementation time at the provider side than we might have otherwise thought.

Just changing the threshold for moving something from a menu to required similarly can imply a functionality change for the vendor because there may be menu items that are just not being implemented even in appropriate venues of care for that item because of the issue of the difficulty of working the capture into workflow. It would be helpful, I think, to get feedback from stage one on what is being attested to. Unfortunately, our timing in the schedule, what Paul put up versus the attestation of stage one makes that difficult. So perhaps there is some ability to use a feedback mechanism such as what you've already used in terms of comments, to the specific question of what menu items do people believe they will be choosing for attestation for stage one, or for demonstration in the second year of stage one?

The next comment relates to the discussion about stage two and the timing requirements and the options that Paul presented, and I'm wondering, are we in fact going to have the same identical set of discussions around stage three? If so, we ought to at least concoct a strategy for how we adopted stage two that's cognizant of the impact on stage three.

Finally, a more general comment, I think as we are moving to a time when meaningful use is not the only or even the major driver for implementing EHR functionality, that is ... Neil Calman's ACO is going to eat meaningful use for lunch state. Our need to be overly specific on certain functions such as care team generation may actually be less than helpful to the industry. That is, where we don't need to substitute an artificial incentive through meaningful use for getting something accomplished, because there are real incentives out there, then there is less of a need to standardize how that thing is being accomplished. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Wes. Let's go to Stan Huff.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
That's a perfect introduction to the things. First of all, it's very welcome to hear discussion that we might have the opportunity to review and comment on the certification criteria. Echoing what Wes said, and others, we've been in the situation where we think we have a better solution than what is mandated by the certification and we need to actually take a step back. The example in our case, we're set up so that we're actually sharing from a single database immunization data with the state and our EHR. So our EHR doesn't store the immunization data in the database within Intermountain. It's a database that's at the state and maintained by the state, so our EHR has access to that data as if it were in our own database, but we're in the curious situation then that that doesn't meet certification requirements because there isn't a transaction, it goes from the state to Intermountain with immunization data in it. And so we're in this curious situation that we're starting to do things to meet certification that actually aren't the best design and so the more that the certification says how you must do things, the more it constricts the creativity of people in actually solving a solution. So the whole idea that we could be more driven by outcomes and more about what we're trying to get done and less focused on how it gets done, I think will be important for fostering creativity and innovation.

Now, the other thing, and this is more radical and strange, is that in doing that kind of review we might ask what is the purpose of these criteria? And what I mean by that is that when I buy a car I don't actually look at who certified the car. I go to *Consumer Reports* or some other reputable group that looks at the track record of how that automobile has performed and look at cost and where it rates in terms of safety and other things, which are based on how it performed. Basically the people who are using that system rather than the fact that it went to some certification body.

Now, I'm not saying that we shouldn't do any certification, but I think actually if we examined our motivation and our motivation was more not about making informed consumers, because I think informed consumers actually do better by looking at things like *Consumer Reports* or reports about what things actually are doing. How people are actually using systems in their enterprises. I think the better motivation probably is around interoperability and other things, and that we would focus on criteria that show interoperability capabilities or outcomes rather than focusing. So it's a call to really examine what is the purpose for certification and I think it should be more for interoperability and creating the sharing of information and less about particular functions or about informing consumers, because I think there are better ways to do that.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you very much for the thoughts. Carol Diamond?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
A couple of comments, also, a great segue to my comments. I was actually going to say that both of our committees are very involved in the weeds, and it needs to be that way. There are a lot of details, specifications, and requirements that need to get done. But I also want to echo something that Stan said as it relates to meaningful use. The objective of meaningful use was to actually improve quality. I think we can get very stuck in the incremental ratcheting up of requirements, whether they be for interoperability or for standards of certification or what have you. I guess it makes me want to ask or wonder whether since the Policy Committee has begun to look at the stage two requirements, whether there's been some taking into account of the National Quality Strategy that HHS released. And whether that might be also a vehicle to try to focus some of our discussions in terms of the measures, the metrics, the objectives of some of this work. So that we're not just in this incremental one-upping the next set of requirements but really focused on addressing those quality goals.

I think similarly to the ACO comment that Neil Calman made, again, there if there could be an alignment of goals then by default the HIT objectives would be aligned because we would be trying to achieve some of the same outcomes and objectives. I just really want to bring us back to those high level, what is it for questions as we go into a phase of down in the weeds.

Now, on the down in the weeds thing, one of the things that I noticed in the diagram, the information flow diagram, is that the policy recommendations go to ONC and then ONC will prioritize for the Standards

Committee, where communications and standards recommendations are needed. The only thing I want to flag—and it's similar to the certification conversation but I want to flag it for some of the new requirements in meaningful use. Which is that there are some elements in the new requirements that have had mixed input that I think could they come back to the Standards Committee for some technical recommendations on how they might be implemented to address some of those comments. It might enable the Policy Committee to have a more informed discussion about how to prioritize them and whether and how to include them.

I don't want to go into the specifics of that, other than to say some of the comments were definitely about difficulties with "implementation," some of it technical. I think there are workarounds or ways to address those either by reshaping the requirements or suggesting a technical mechanism much the way has been suggested for certification that might make those requirements very, very achievable. I just put that out there as a question or an opportunity for some of that back and forth to help inform the Policy Committee in their deliberations. Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific. ... on that second issue let's come back to Beth and Doug's upcoming conversation, because I think that interflow of information is going to be a critical part of that. Josh, did you want to make a comment?

Josh Seidman – ONC
I just want to respond to Carol's first point. Actually, at the meeting last week of the Policy Committee Peter Lee presented the National Quality Strategy right before the meaningful use discussion, which is very helpful, I think, for the committee and in fact it actually led to a very good discussion about thinking about the stage two and future stage meaningful use criteria and objectives in that context. Because of that, the Meaningful Use Workgroup has actually scheduled another full day meeting, which will be May 3rd, and staff will be doing a cross-walk of the National Quality Strategy, some of the things from the ACO proposed rule, and the current Policy Committee stage two criteria so that we can put all of those things into context. Again, as Farzad mentioned before, the ACO proposed rules really is a proxy for all the other things that are being discussed as a result of delivery system reforms in ACA.

Kevin Hutchinson – Prematics, Inc. – CEO
Jonathan, I have my card up when we're ready.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay. Let's take one follow up from Carol and then we're going to go around the table with the cards that are up and make sure we get to the next discussion on that interflow.... Go ahead, Carol.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I was just going to say, Josh, that I think it's really important that that context be the overlay to the meaningful use requirements from a public perspective as well, in terms of how providers and the public see objectives of "meaningful use." And that we not get lost in the features and functions of technology or the adoption rates or some of the other downstream metrics.

Janet Corrigan – National Quality Forum – President & CEO
Jonathan, I have my card up too.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay. If this is directly on the quality agenda points, why don't you go ahead with that right at this time.

Janet Corrigan – National Quality Forum – President & CEO
I should go ahead with it?

Jonathan Perlin – Hospital Corporation of America – CMO & President
If it's directly responsive to the quality agenda that Carol just brought up.

Janet Corrigan – National Quality Forum – President & CEO
Yes, it is. I continue to be a little confused because when I look at the tiger team organization, the particular areas that were targeted by the various tiger teams and the Policy Committee, they parallel very, very closely the six areas that were identified in the National Quality Strategy, and so that's terrific. We essentially have already done a great deal of work that is very consistent with the National Quality Strategy, and indeed I think that much of the quality community that has been doing a lot of work on measures, whether it's for public reporting and for payment programs, is also very well aligned with the National Quality Strategy. Those six areas are very close to the National Priorities Partnership priorities that were put out two and a half years ago, so alignment has been achieved to a great extent.

However, having said that, what we haven't seen is what would really be a transformative shift in the kinds of measures that we're using. By that I mean the patient reported outcome measures that I think all of us want to get to that would really begin to capture the health functioning and also the health risk appraisal and health behaviors. If we could make that kind of a move and really make a commitment to gathering those types of data on a routine basis—and it needs to be information that is collected not just when patients are having an encounter with the personal healthcare delivery system. But rather when it is most relevant to collected, assuming that most of these patients have chronic illnesses, we really want to be looking longer term over the entire patient focused episode. I still don't quite see that we've made that transition. I don't hear that coming from either the Policy Committee, and I certainly don't see it in the Standards Committee work.

We would really, I think, have to be devoting a good deal more attention to how we're going to capture that information through various apps or other means, PHRs, we've got to have mechanisms for capturing that information from individuals, not just when they're in a face-to-face encounter or somehow a part of the healthcare system. I think we have to make a real commitment to standardizing how we collect the health behavior and health functioning types of data elements. If we could do that, it would open up a huge opportunity in terms of the performance metrics. It could be used not only in meaningful use but also in the payment and the public reporting programs, and even more important, provide the kind of immediate feedback to clinicians that I think could have a very significant impact on just moving the healthcare system overall to having a more patient-centered approach that looks at outcomes.

So I don't think it's really an issue of the National Quality Strategy or having the right priorities, we've got it and it's a terrific piece of work. It's wonderful. We can align with it, but we can really only get to where we want to go if we make that real commitment to move outside of EHRs to really collect the PHR information or the patient reporting data in some fashion, and to do that in a very aggressive way so that we're not looking at the same problem three years or five years out.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific comments. I was just going to hold this until the end, but I think it's worthwhile and I want to make the circle, and Kevin, I've got your card, but two observations. First, I think that body language implies just general agreement about the aspirations in terms of the point Carol made for quality, and then Janet reinforced. That said, I would just note in all the comments made that there is an implication of interoperability, that longitudinal set of outcomes that Janet referenced.

The other is that I think we heard a theme with Wes and Stan that when one really wants to get to the functional outcomes, the implication behind that is that these systems exist. I think one of the things to celebrate in contrast to our first meetings a couple of years ago is how much the ecosystem has changed in terms of there being the presence of systems that even if they don't have the capacity, at least there's the nascent emergence of the technical foundation for that ecosystem. But that foundation is not full yet and so we're talking about functionalities at the same time that part of the rationale, the framing rationale for HITECH in the first place was to encourage the adoption of technology. That's that structure process outcome, or the arrow diagram that we remember. It is terrific that we're talking about the attributes of two and three. I think one of the things we have to hold ourselves accountable for is making sure, and I think this point was well made by Wes, that as we contemplate two we're also thinking about three. Because there's a world around that's looking to say what does this mean, as we try to thread the needle not only for the immediate but the longer term, that we remind ourselves that there are different stages of

evolution in different places, and as we create these goals we're also trying to pull along the emergence of a foundation that is not yet complete.

So I'm thrilled that we're talking about these secondary attributes, but would just caution ourselves to remember that this is a time where physician offices, hospitals, long term care facilities, patients themselves are beginning—certainly have not completed acquiring the technologies. So a lot of what we're talking about are interactive properties of that emerging ecosystem or ... challenges that in this next thread let's remind ourselves we've got to propel that ecosystem as well as support the attributes that that ecosystem provides. David McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Thanks, Jon. That's a great setup for my question, which is for Paul Tang, if he's still on the line.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I am.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Paul, in your high-level summary of comments slide where you summarized the 400 and some odd organizational responses into those which had strong support and mixed support, I noticed that there wasn't any mention of cross-provider interoperability. There's provider to patient downloads, uploads and secure messaging, but there wasn't any mention of cross-provider, be it either direct provider to provider or indirect through regional exchanges. I'm curious if you just didn't mention those because they weren't relevant comments, or because those are not contemplated as part of stage two, increasing requirements in that space? Could you pick up on that?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Sure, absolutely. Thanks for the question. These high level summary comments are by no means comprehensive. We do want to emphasize that health information exchange, one of the ways, as you know, in stage one is the testing requirement, just if you tested your EHR has that function capabilities. We strengthened that to say that we wanted to see actual exchange with not in the proposal we said three, I don't know that the number's right, but three clinical trading partners. Healthcare is local, you have local needs, and we don't mean to make you do things that don't support your local mission, so find the folks you need to, and everybody has those folks, and start really exchanging with them. So that's where that would come in. Then we have these other documents, artifacts that say can we get information, these minimal data sets of information, whether for referral or care coordination, with a clinical emphasis on care coordination, and the technical is that you are interoperable amongst providers.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Okay, great. Thanks. That clarifies .... I was surprised to not see it brought forward and I'm glad to hear it's still there. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's take three last comments. Let's go to Walter Suarez and then Kevin Hutchinson, who's on the phone, and then Chris Chute for the last word.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
My question is about the timing and the synchronization of all the different steps and engagement that will have to happen before a final rule is issued. I think it's very well-known that vendors usually don't engage in the development of new product or upgrade of product until they see the actual final requirements out there. I've been sketching out the sequence of all the items and following your slide number eight, and you highlight a number of these timing issues. But my concern is really the fact that we're probably going to have a very compressed time between the moment when the final regulation on certification standards is issued, and when the implementation will have to happen. All the activities between the two the vendors will have to do in terms of development of the new upgraded product that meets the requirements, that meets the meaningful use expectations for stage two.

Going back to the first stage, in January of 2010 the interim final rule on the certification and standards was published and then the final rule was issued in the middle of the year last year, July of 2010. But entities had basically up to the end of last year, last year, and then nine more months during this year because this first year was really only a three month period, but that's probably not going to be the case except if there's proposed options on stage two timing. On top of it, of course there's not just engaged the development of this regulation but the involvement of the Standards Committee in helping define those standards and the certification criteria, and then NIST engagement in creating the certification scripts. If things were to be done in the schedule that we have today and the requirements were to be set to start for stage two January of 2013, there would probably only be about six months between the time when final regulations are done and the actual start of the next wave of requirements happens.

So I wanted to hear about that sequencing and that compressed timing of both the development of the regulations and then the actual deployment of stage two by vendors and providers and what kind of discussion and comments have been made around that.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Those are very fair points. I was sketching out myself a sequence of timing, and if you don't mind, let's take that, Doug, into the next section where we're going to talk about the flow back and forth, because I think all of us I think palpably felt our blood pressure rise as we contemplate that compressed timeline. But I think we'll get more insights ... the next discussion looking at the interplay with the Policy Committee, and I think you've done a great job of summarizing the challenge for, I believe it's now ONS (Office of No Summer). Let's go to Kevin Hutchinson. Kevin?

Kevin Hutchinson – Prematics, Inc. – CEO
Thanks, Jonathan. I just want to get a real world example of—Paul talks in the early stages about workflow and the impacts we have to think about workflow and meaningful use, and especially stage two as we get more into the interoperability and exchange information, but one item that was mentioned in the slides was ePrescribing for discharge medications. Just to give you a real world example where the patient, if we don't think about this clearly, can get stuck in the middle, is we looked at this several years ago of how to do electronic prescribing for discharge meds and ran into a real world workflow issue where discharge medications are typically brought into the pharmacy, dispensed. Then when a follow up visit occurs with the physician, usually not the attending but some other physician that had been referred out. There's in many cases a change of medications, whether it's changing dosage or actual change of the ... itself in the therapy.

In many instances the patient's back in the pharmacy two weeks after discharge from the hospital with another drug order and from the follow up physician. Then the PBM is denying that order because they've already dispensed 30 days of a different medication and it puts the patient in a very awkward position because they can't get that other medication for another two weeks until the first 30 days of that medication has been completed. So in looking at that workflow, it's really important that a prescription that comes from a discharge medication is identified as a discharge medication. And that the follow up physician is also identified in that order so that the pharmacist can make sure that the follow up physician is in agreement with the medication order so that we don't put the patient in the middle of that changing order.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great counsel and very practical in terms of we'll also carry into the next discussion about the interplay between policy and standards as this evolves.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
John, can I put my electronic card up?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Jim, we're going to take you as the very last. We're running over on this section and we have a pretty robust agenda.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I'll be quick. Two questions, one, a follow up on Kevin's. We were ready to start sending electronic discharge prescriptions and found that almost no pharmacies are able to process electronic cancellations and since discharge meds are often cancelled before the final discharge we felt that was a patient safety issue and dropped the project until pharmacies are able to process them. But, from a timing standpoint, I would appreciate understanding from Paul how the Clinical Quality Workgroup's deliverables are meant to fit with the schedule that he presented in terms of the Policy Committee's considerations.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Good. Jon, can I summarize a few of the things I've heard as part of answering Jim's question?

Jonathan Perlin – Hospital Corporation of America – CMO & President
That would be terrific.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
One, I wanted to see if I could propose a mod to Neil Calman's quote about ACOs eating meaningful use for lunch, because it unintentionally sets it up as a competition and I think we've all agreed that actually what we're seeing and witnessing is there's a real important and deliberate attempt to align all these things. So if I could maybe modify a culinary metaphor, think of it more as meaningful use being the place setting for ACO concepts and the National Quality Strategy, because it really provides the tools for those things. At any rate, that's an overarching comment, but I think it actually describes what we're trying to do.

To address Carol's thing about the National Quality Strategy, it turns out that between the March and the April Policy Committee is when the ACO, NPRM, and the National Quality Strategy final came out. As Josh mentioned, we intend to go back and reconcile some of even stage one's approach with the new Quality Strategy, so that is something we wanted to take into account and it could produce some differences. Another piece that relates to this is somebody pointed out the compressed timing we have between when we, the Policy Committee, has to put out the recommendations to CMS and ONC, and the lack of feedback from the field, ... We have to remind ourselves that we have ... for the middle of the year but then HHS has six months to produce their NPRM, that's the tentative schedule, and then another six months to incorporate the public comments into their final rule. So there's yet another year that they will have access to all of the input that we don't have before June, so that's some consolation or comfort.

One of the ways I think we may be able to work between the two groups is we have already generated a list of things that we either want to ask the HIT Standards Committee, or get their input to help, as someone pointed out, shape some of the proposals we have for stage two criteria. Maybe what we want to do is hand you off a set of questions if you have a way to process them and provide feedback back into this stage two requirement building development process we're in just to try to synch them up. I think it would be extraordinarily helpful if you're willing to receive those.

Then that brings me to Jim Walker's comment. The clinical quality measure, we do have a separate workgroup. Jim's on that. They're developing tremendous recommendations. A lot of it will have to be stage three just by the nature of the, again, the lead time for development, that's why Janet Corrigan's plea for more emphasis and even support of quality measure development, particularly in the patient reported outcomes is relevant. So we may not be able to catch it in stage two quality measures, but hopefully in stage three.

Jim, we imagine the Quality Measures Workgroup's resolved to go into the NPRM process, the rule making process of HHS, and it probably won't make it by the June recommendations of the actual qualification objectives, and that's only the nature of the compressed timeline. Does that help?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Yes. All I want to know is understand the ground so that the Clinical Quality Workgroup has a clear task and the deliverable date so you don't see us providing any feedback because we really don't have that much to feedback on to before June the 8th?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes. We would accept and would love to have any of that. My understanding is that the timeline was not a practical one.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I think we're meeting regularly and we can certainly identify questions with those measures and get them to you. Maybe we can talk off line.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, without bothering this group.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
But we want to get it as soon as possible, but just wanted to let people know there is more time ... our final recommendations where input could be incorporated by HHS.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
All right, thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Chris, ...

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I'll try to be very quick. ... things largely said. I simply want to echo and emphasize what you said, Jonathan, and indeed what has been mentioned about quality, and that is let's not lose sight of the prerequisite, almost foundational nature of the interoperability because interoperability has, in and of itself, goals that are really required, as Janet said, to achieve the larger scale of quality. Furthermore, it has meta goals and outcomes that actually have value over and above contributions to quality, specifically the whole spectrum of secondary use, the best evidence discovery, the cost reduction in terms of understanding what's happened elsewhere in a computable and intelligent way, and I simply want to reemphasize that foundational nature of interoperability.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great comment and great by way of segue. I appreciate not only the intellect behind this discussion but obviously the passion as well. As we segue into the next conversation, there were a number of points made, which I'm not going to try and summarize, but clearly there is a very resonant sensitivity to first the example that Kevin Hutchinson gave in terms of workflow and that Jim Walker provided in terms of e-cancellation. In fact, we need to make sure that our aspirations to calibrate it to the state of the ecosystem. Chris' last comment about the interoperability as being foundational is really very, very helpful in terms of framing the challenge of stage two, which is encouraging the foundational aspect at the same time that we're trying to articulate those things that are more aspirational in terms of the values of improved healthcare.

It was also pointed out by many that this is compressed time frame and particularly challenging in a couple of dimensions. First, that we're having simultaneous discussions about the changing healthcare ecosystem more broadly and the incentives that provides for behaving in certain ways and the relationship of those behaviors to the supportive capability of health information technologies; second, the aspirational nature of supporting better outcomes; and third, the evolution of the foundational aspect in the first .... Couple that with the particular set of activities that we're supporting with standards and recommendations for testing and linkage with the policy objectives, the idea, and I think Carol Diamond puts it nicely, the interplay that this just can't over the transom and ..... It has to be really an interactive, an ongoing process, and I think that was just a terrific conversation, terrific counsel that everyone's

sensitive to, and also a setup for this next conversation, and John Halamka's terrific guidance, that with all ... a calendar of how these activities will be sequenced and when they occur.

With that, I'm going to turn to John.

John Halamka – Harvard Medical School – Chief Information Officer
We will make up some time because I know Jamie's report will actually be relatively brief. He has to run off to another meeting anyway, so we will make sure we have appropriate time for you, Doug, to discuss what it is we're going to do, how we're going to do it, and how we'll organize to do that work. So let me just turn it over to Doug and dive into the presentation.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Thank you very much. This has been a very rich conversation. We have Steve Posnack with us, because one of the things that I wanted to make sure that we understand is in some sense the way the HIT Policy Committee and the Standards Committee and ONC are all going to be working together. So we have here a slide that is part of the formally vetted and approved way in which these committees work together. And I wanted Steve to just comment on that and just lay the foundation about how all the various moving parts that we've got between Policy and Standards and the S&I framework and the ONC, how all those pieces fit together, so with that, Steve.

Steve Posnack – ONC – Policy Analyst
Thanks, Doug. Not to preempt the summer camp discussion, but I think Doug and I are going to be your counselors over the summer. I'll be the guy that says no, and he'll be the guy you can go to, to get yes. So if a picture's worth a thousand words it's probably actually close to about a thousand on there, but this represents Section 3001, 3002, 3003, and 3004 of the HITECH Act, illustrative of the relationships between the advisory committees, the national coordinator, and the secretary through which the whole process by recommendations from the Policy Committee come to us. We distill them. We package them back up. We come back to the Standards Committee and present the priorities that we've heard from the Policy Committee, you all chew on them and then recommend. I think one of the things that we've already had a rich discussion about, like Doug said, is that your responsibilities include recommending to us, among other things, standards implementation specifications and certification criteria.

So previously, I think under a lot of the expedited time frames that we had with setting up all of the infrastructure for stage one you all didn't have a tremendous amount of time and opportunity to recommend certification criteria, and that's one of the areas where your input could be very valuable this time around. When things come to the national coordinator we have a corresponding responsibility, which is in Section 3001, to go through those recommendations, juxtapose them with everything else that's a priority in the department, other policy priorities, and endorse standards implementation specifications and certification criteria and pose them to the secretary for her consideration. She has another process that she goes through. All of these specify upward bound in terms of the timing that the statute includes, we hope. We don't expect that it will take this amount of time because if you actually tried to factor that in in terms of when you would make your recommendations this time this summer and you look towards the upper bound, we wouldn't get a final product from the secretary until late in the year. Obviously that wouldn't synch up with our rule making aspirations. This is what the HITECH Act looks like in a picture, and we will live by it.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Thank you, camp counselor. Why don't we go and we'll do the other presentation? HIT SC this summer will stand for Health Information Technology Summer Camp. So we have a lot of work that needs to be done. We've done a couple of things since the HIT Policy Committee met. We'll talk a little bit about the metadata analysis that will happen after Paul gets his presentation. But I also wanted to go through and take a look at the draft recommendations for the Policy Committee and see if we couldn't get a straw man out there about what are the kinds of things that we're going to have to do over the summer. What does the work look like? It's not a complete list. There are probably things that are missing off of this. But I think it gives us a sense of the scope of work that we need to do and what are the kinds of things that we've got to try to get accomplished over the course of the next couple of months.

To Steve's point, one of the things that's going to be important as we think this through is that we really do need to analyze the standards implementation of the HIT Policy Committee recommendations. This is going to be helpful as we prepare for meaningful use, we need to identify gaps in the standards that are there, we need to triage some of the standards work in much the same way that John Halamka was talking about in the buckets that they would go through. I think it's important to recognize that we have a number of tools at our disposal to be able to prepare for meaningful use stage two, identify the gaps, and do this triage. You folks have the opportunity to hold hearings if there are places that you need to get more information from the public on or that you feel is an important aspect of making recommendations. We have the ability to use a federal register and to post for comments things that we need to get additional public input on. We have Wikis that people can provide comments. You can set up new working groups, and we do have the S&I framework that will help us as well. But I think it's important to recognize that we, over the course of the summer, need to use all of those tools at our disposal to get the kind of input that we need to be able to make appropriate recommendations with that.

So everything that comes from policy doesn't necessarily have to go through the Standards and Interoperability framework. In fact, we have lots of ways that we can get public input and the like. But we have to think about the entire set of tools that we've got in our tool kit and leverage those appropriately so that we can get the public input that we need to make good recommendations.

What are some of the action items that we have for meaningful use? There's this refresh and reload. We have to recommend revisions to the adopted certification criteria. This is to Steve's point that we need to make sure that we take a look at that and see if there are things that we need to recommend in terms of revisions or additions. We need to recommend new and updated standards implementation specifications to associate with the adopted certification criteria, so if there's a certification criteria are there standards that we need to identify that will allow us to achieve those goals or the implementation specifications that are going to be important there as well. I think to that point, there are some of the policy recommendations that are functional, that say we want to be able to have this function available. There are some that are interoperable, if you will, that say we want to not only enable this function, but we want to do it in a way that allows the exchange of information based on standards, and we have to be clear about those distinctions.

So we can't probably wait until June to get the final recommendations and then begin our work. I think we need to start now in thinking through these draft recommendations, identify any new certification criteria, begin looking at the standards and implementation specifications. I think to Carol's point, making sure that we've got a good interplay between the goals of the Policy Committee in terms of what they recommend and the way in which that can be supported with the standards, implementation specifications and certification criteria. So we have an opportunity, I think, to start that dialogue and get that feedback and conversation going.

When we think about what we need to do, I think we're going to have to do some fairly rapid triage so that we can put our time, money and energy and to take a look at all the tools that we've got and apply those appropriately to the task at hand. There are three or four buckets, depending on how you want to break things up. Bucket A might be performance measures only, in which there are no standards that are needed but we need to be able to identify within an electronic health record some function that we want to be able to support. Bucket B might be that we believe that there are sufficient standards and implementation guides that are out there that are in use that have been identified and that would support the policy objectives that we might have. Bucket C is, there may be existing standards but there might not be an implementation guide that's identified. Or the implementation guide may not be specific enough to be able to create the criteria that we'd like to achieve our policy objectives. Or, existing standards or implementation guides are there, but we need additional public input. Maybe there are two alternatives that might accomplish the same goal and we need to figure out how to merge them together, or we need to figure out how to resolve a standard that may require some additional attributes or some additional input with that. Certainly some of the work that Dixie's done on the certificate, the X.509 as an existing standard, is that sufficient for our goals? Are there new attributes that are required there? D, is there are

no standards or implementation guides that have been identified, or the existing ones require really substantial input.

So if you think about the continuum, we probably, over the course of the summer, need to focus on things like the B and C. And maybe help us identify the A and D so that if there's something that we think is close but not quite there and we think we can get there with some concerted effort, that's kind of Bucket C. We need to know that now so that we can put that energy in and try to come up with something that would be supportive of a policy goal. It could be that some of the stuff in Bucket B is sufficient standards and implementation guides are identified. We might be able to tick those off pretty quickly by saying here's an implementation guide or here's a standard that we think would support this and we don't think a lot of extra work is needed, and maybe we can get those taken care of early with things.

So I think as we think about the work ahead from the Policy Committee recommendations, we need to think about how can we get these buckets? Now, one of the things that my team did, and we had input from a variety of people, Arien Malec was instrumental in trying to help put some of these buckets together, is we've made a first pass at what some of the criteria might be and what bucket it might fit into. We likely have made mistakes. We probably don't have everything exactly where it needs to be. But we need a straw man that people can take a look at, because a blank sheet of paper sometimes is really hard to know how to begin. Our hope is that we can accelerate the process by giving at least some straw man there and saying does it fit in this bucket? If it does, that's great. If it doesn't, let's try to figure out where it might fit.

So we've got a couple of slides that have gone through some of the criteria and some of the work that the HIT Policy Committee has already done and tried to put it into these buckets that would help us organize our thoughts. Bucket A, performance based measures, so things like CPOE for laboratory and radiology, is this an entry process only or does it require electronic transmission? If it's just something that we want a functionality there, maybe we don't need to have an implementation guide or a standard. There may be a certification criteria that we want to make sure is accomplished there, but we need to take a look at that as well. Interaction checking for medications; recording demographics, maybe that's an entry process only. Do we need to include other kinds of things if there's race and ethnicity, are there value sets that we need? We need to step through that. Maintenance of problem medication allergy lists, recording smoking, vital signs, the ability to implement a clinical decision support rule, again, a performance based measure now. It may be something that as we look to stage three we may want to think about what are the things that we would want to help support that. Recording advanced directives, I don't believe there is currently the need to exchange that, but to be able to indicate that there's one that exists. We need to talk about that. Generation of patient lists. The ability of physicians to document their notes, electronic tracking of medication administration, this is eMARs, is that a function that exists within an electronic health record that we don't want to prescribe or identify standards for how that does, but just functionally what the certification criteria might look like. Patient education, patient preferences for communication medium, medication reconciliation, we can talk a little bit about the transitions of care based data sources, about how to think that through, and then recording the care team members.

We took a look at these things and said, many of these things probably require certification criteria, but if they don't involve interoperability they may or may not require standards for how we do those things. I think we just need to go through this list and see, are there things here that need to be moved over into, there's an existing standard and we're all good to go. Or maybe there's no standard at all and we may need to start some initiatives there. But clearly if there's no standard to do these things and we think there's a standard that may need to support it, we may want to think about how a performance based measure that has a certification criteria currently—kind of an attestation approach or a visualization—may be able to gradually over time move into something that has more explicit standards that underlie it.

Bucket B, sufficient standards and implementation guides may exist, so things like recording demographics, maybe there's the value sets from the IOM categories that we can use that will help us record those demographics in a standardized way. Reporting the CQM electronically, we've got PQRS that might help us and that we also may have a CMS implementation guide that can help us there. Drug formulary checks, there's the NCPDP eligibility and benefits that may provide a standard for how to do

some of that work. Submit immunization data, we can use a vaccination record update from HL-7, and maybe you need to begin working with the CDC immunization working group to make sure that if there are implementation guides that are necessary or revisions we can begin doing some of that work.

Submitting electronic laboratory reporting, HL-7 has some standards that exist for that and there is an existing implementation guide. We hope that that will be harmonized in a final ambulatory lab implementation guide as part of some ongoing work within the Standards and Interoperability. Yes?

M
That's NCPDP formulary and benefit standards.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Oh, I'm sorry, formulary and benefit standards. Thank you. We had a week so there are, again, mistakes in here with this. But clearly there are some activities here that we're pretty close and maybe we just need to step through and identify some things that will help us with standardizing the work.

Bucket C, these are things that maybe we need a little bit more input, so things like incorporating laboratory results. We're working right now within the Standards and Interoperability framework to try to refine how we do laboratory reporting. We probably need to identify a LOINC subset to begin honing in on the vocabularies and terminologies that we might look at. So we're well on the way with this. We hope to have some of the drafts of the work of the S&I framework ready come June to give us a little bit of time to have some discussion about that as well. Things like providing an electronic copy to a patient, health information discharge summary, clinical summaries. We've got what we call the transitions of care initiative that we're looking at CDA, CCR, and the green CDA, trying to figure out if we can consolidate that into a common way in which transitions of care between different office visits or from hospital to outpatient setting discharge instructions, how those things can be summarized. We will probably need to, again, identify vocabulary subsets as part of this and we hope that we can provide to the committee some draft work from that framework come June. Again, providing summaries on transitions of care, this is sort of related to that. I think we put those pieces together. Care plans were something that was highlighted in the HIT Policy Committee work and that may be something that we can fit into this transitions of care. I think we need to make a decision as to whether we can do that as part of the transitions of care work, or whether this is something that would be in a Bucket D, where we don't really have a standard just yet to help us with that.

Syndromic surveillance, there's an implementation guide. We initially adopted one in meaningful use stage one, but then decided that additional work was necessary. I know the CDC has been working on that and we may need to revisit that as well. There are privacy and security assessments, and Dixie Baker has been tremendously hard working in doing this and there are pending recommendations that are going to come from the tiger team as well, and we need to think about how those pieces are going to flow into the standards that we might adopt.

Bucket D, things that may require substantial input may be things like clinical physician order entry, laboratory and radiology, things like orders that may need to be transmitted around laboratories. So HL-7 can help us there but I think we may need to at least discuss amongst this group as to whether we're ready to adopt a particular standard or an implementation guide. Or whether we need to push that out and do some additional work, knowing that it's important, but knowing that we have some very aggressive timelines in terms of what we need to do.

Other things that we need to, I think, discuss. We probably need to have some discussions about transport, so transport mechanisms for lab, for transitions of care. We have the Direct Project. We have specifications in the NW-HIN that uses a Web services approach, or do we want to make it performance based, in which we don't require a transport but we provide tools that will help people achieve meaningful use without making it a criteria that we would hold people's feet to the fire. I think we've got Direct, we've got certificate work about the X.509 standard and other work within the S&I framework that we're working on. I know I'm working very closely with the NW-HIN team to try to take a look at our specifications and create more modular specifications so that we in fact have a whole suite of things that are currently part

of the specifications. In those production pilots that are ongoing, what are the things that are really robust that people are really using, so profiles that they're using, and can we create more modular specifications that allow us to adopt those as part of meaningful use. I think we're going to need to have some public input and discussion here for that.

Sending patient reminders, Web portal and timely access, you know the notion is if you want to have timely access do we want to use a direct protocol to send that to a personally controlled health record. Or is it performance based in the sense that we want the ability for someone who wants to meet meaningful use to have a portal that would allow them access to that as well. So I think we have some discussions there.

Online secure messaging, again, we can use Direct, NW-HIN performance based approaches. A test of health information exchange, again, getting those conformance tests and putting them together as a conversation that allows us to test for interoperability becomes important. We've already had some discussions, both within this committee and within policy, around directories. So there are standards like LVAP that can help us, but is there extra work that we need? Do we need to define the data that goes into an LVAP framework so that we have the ability to have standardized services and standardized expectations for the data that you might get out of those directories?

We sat down and we tried to figure out, well, what is our summer going to look like? What are the camp activities that we have scheduled as part of Camp HIT? And this is just a straw man that tries to take at least some of those activities and spread them out over the summer. I think we probably need to have some work after we get input from this committee to figure out how to move things around, and if we've got this wrong how are we going to do it? But it seems to me that today we're going to talk a little bit about the PCAST Reports and we will present some of the initial metadata analysis that we've done, taking a look at existing standards and trying to identify from those existing standards what might fit in terms of provenance, patient matching, and granular consent. We may need to do some work on that between now and, say, May, where we can take a look and do some final metadata analysis and take a look at what of those things might make sense to include in meaningful use stage two.

We also, I think, need to review our summer work plan, and this is just beginning that conversation. But we have some existing standards that we may want to review around drug formularies, around ePrescribing. There are some things that may be emerging standards about longitudinal care plans, directories and certificate interoperability that I think we've been talking about and I think we may need to begin thinking about is it appropriate for us to get a standards and interoperability framework activity that will help us provide any input that might be necessary.

In June, we thought that there was a variety of things that we might want to take a look at there, so a list of care team members as a criteria, the notion of hospital portals. These Web portals versus PHR transmissions, advanced directives, what are the value sets that we need, is that something that needs to be part of a transition of care or a C32, a box that needs to get checked that says, yes, it's there. No, it's not. Those sorts of things. There was discussion and support for family history recording, so is there an existing standard that's out there that we can use? If so, that would be great. If not, is this a performance measure or is it some additional work that needs to be done? Reportable condition standards, immunization and lab reporting to public health agencies, again, all are things that are in the pipeline that we have to probably have some discussions on.

We hope that by the first part of June we should have some preliminary results out of some of the initiatives that we have within the Standards and Interoperability framework. It seems to me that either in June or July would be a good time for us to come back to this committee and see whether we're on track and whether there are things that we need to do different within those. That includes laboratory results, transitions of care, and I think at that point too we will have a more modular approach to the Nationwide Health Information Network specifications. I think we will have some boots on the ground experience with Direct as well, and I think it's an opportunity for us to look at those things.

August we thought might be a good time for us to spend some dedicated time on vocabularies and terminologies and value sets, not that we would wait for August to do all of that work. Yes, I have it all there, that's you, Chris, we just need you to figure that out. But as part of all of these initiatives and all of this work we need to be identifying are there vocabularies and value sets that we need to be able to include as part of laboratory results. Are there LOINC code subsets, transitions of care, are there ICD-9, ICD-10 and SNOMED codes that would be appropriate, the most common problem list or the most common kinds of procedures. In some sense in August I put that there, if for no other reason as a placeholder to say that this is important and I think we need to have some dedicated time to look to this.

Certainly within meaningful use stage one we talked about how we adopted optionality in some of our vocabularies and value sets, saying well, ICD-9 or SNOMED are going to be okay. I think going forward we have to ask the hard questions about can we converge those and identify for a particular domain a vocabulary or value set that will be the standard going forward. Then having done that, what do we need to do to help make people successful getting to meaningful use, how can we make an incremental approach with tools that will make people successful in getting to those consolidated sets of standards.

Then in September we will have what did I do this summer review. That's the catch-all, because we're getting late in the game for what we need to do with regard to the regulatory process and getting the next stage of meaningful use together. But we've got a very aggressive time frame here. We may need some catch up time. And if there are things that are still outstanding that we've triaged toward the end of the summer, we have an under specified step there.

With that, there's really not a whole lot that we have to do this summer. We probably will want to spend some time I think now talking about how we're going to get through this work. I told you that I had this scary list. Now you have one. And we just need to try to figure out how we can collectively help support the goals that we have from a policy perspective, the goals that we need going in from stage one of meaningful use to stage two, and with that, I welcome all the cards going up.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Will there be swimming?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
You have to pass the criteria.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, there you go. As I look at this, I'm sure there's going to be many comments on potentially rearranging some of these categories into something that will stage the work in a more logical fashion based on work we already have in process. But certainly as I look at your needs discussion slide, an example, Dixie and team and Walter are already working on direct reissues and you framed up a question quite nicely, which is LDAP, the standard everyone uses. It doesn't, however, meet the requirements that we think in a Web connected world with HIEs that you'd actually want LDAP as it exists today. Does it need to be extended or replaced? What bucket do we therefore put it in, B, C, or D? I don't know the answer but I'm sure you guys will figure it out.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
C.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, so there we go. Done. See how fast this goes? So why don't we open up the discussion to what is your reaction to this work list, what are your reactions to the process of bucketing, and the next several months ahead. We'll go around the room. Chris, I think you put yours up first.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Thank you. Obviously, there's a flotilla of comments that I won't make. I'll focus on—

M

At least it's not an Armada.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Exactly. I'll try to focus on something a little more specific. I was intrigued in your spoken words, Doug, that you asserted that value sets were pure elements of intrinsic standards, a position I agree with. Yet, in your writing you implemented them or referred to them in the context of implementation guides. I think philosophically as we tackle this kind of list the real question is when do we take on the dreaded vocabulary problem? Because many of us, as I think everybody in this room knows, I personally believe that interoperability absent semantic specification is not that useful. It leads to the position that value set binding, if you want to call it that, should be an intrinsic component of the standard specification process, not almost an optional afterthought that is loaded into some implementation guide post fact, but intrinsically bound at the specification of the standard itself. If that's true, that would have impact on some of your timing, some of your evaluation, and indeed some of your bucket assignment. I'll leave it at that.

Jonathan Perlin – Hospital Corporation of America – CMO & President
...?

M
I agree with putting it in buckets. It makes it very easy for me. Bucket C, I'd like to ask a question and then I'll volunteer something. Bucket C, we in long term post-acute care take the transition of cares under our wing and in Bucket C it's to the family and all that but we also take it as that's part of our obligation in transferring care to another provider, home care, or to a skilled nursing facility. Even in our CCHIT criteria, which for certification we worked on and published last August, we put the CCD in there. I was wondering whether, I know at times we've talked about CCR and CCD, is the CCD left out of this, because we're really concentrating on CCDs and not the CCR, or is that just an omission or we made a decision that we're doing the CCR?

Then the second point is, I volunteer all the sources at my disposal, which are a lot, of all the different associations with long term post-acute care to help you on these items. Also to help you on the list of team care members and offer all the resources, just so we're in harmony when some day we say it's not only the family that gets the patient transferred to, but to a skilled nursing facility and to a home care. Or an LTAC, or to an IRF, or any other alphabets that we represent.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Let me just comment. In meaningful use stage one we adopted two standards, CCD and CCR, with C32 as the implementation guide for the CCD. I have not put on here CCD or CCR. I put on here transitions of care. That is an initiative actually that is intended to have participants from the CCR and the CCD community come together and agree on what a transitions of care document should look like. What is I think exciting and I think nice about the work that they're doing is that there is an initiative up front within the HL-7 community to create what they call a green CDA. Which looks remarkably like a CCR in terms of the way in which it presents the information that doesn't have as much of the complexity that the CDA templates have. I think that team's been doing remarkable work in trying to resolve the issues between a CCD versus a CCR.

The goal I think that I hope we all share is that whenever we have options where it says CCD or CCR, or where it says ICD-9 or ICD-10 or SNOMED, any time we see an "or" what we really mean for a vendor is "and." So we create exponentially more work every time we add more options. Options don't make it easier, it makes it harder. So sometimes what we need to do is just to try to begin to converge our work, and I think that's what the transitions of care is really intending to do. It isn't as if we've decided to go with one or the other. In fact, what we're trying to do is to get the input from the community about how we can converge and start reducing some of those options that we might otherwise have.

Jonathan Perlin – Hospital Corporation of America – CMO & President
It would be wonderful if we could achieve harmony and it all could come together with one transition of care document and one implementation guide.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I'd like to buy the world a Coke.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Indeed. Perfect. Carol?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
My question or comment is actually not about the stuff on your slides but about something that's not. I know we're going to talk about the PCAST Report later, but the administration also released the National Strategy for Trusted Identities in Cyberspace (NSTIC), as I've heard it already acronym'd. Because on the tiger team we certainly spent a lot of time on issues of identify and authentication, it's certainly an element of some of the meaningful use stage two aspirations. I'm just wondering how that's going to factor in, or how should it factor in to some of the work that you outlined and also some of our work.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Obviously, the Privacy and Security identity management is a critical piece to all of this as well. I think to the diagram that Steve discussed before, part of the process that's outlined in HITECH is that recommendations come in and then we try to make sure that they're aligned with administrative policy directions and what the other federal agencies are doing. So clearly we will need to consider that as we move forward. We can add it to the list. I think where it fits and how we do that, whether it's a B or a C or an A or a D, I don't know. But there's a whole series of activities that I think are probably not even on this list that probably need to be. It was just getting too scary, I guess, to include all of those.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
The only reason I raise it, and I want to caution, is that we shouldn't in some ways reinvent the wheel in order to achieve some of these objectives if there's some movement or traction there.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
We don't have time to reinvent the wheel.

Jonathan Perlin – Hospital Corporation of America – CMO & President
May I quote you on NSTIC as the new acronym?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I think so. I've heard it before.

M
I've heard it before.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes, okay.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Carol gets the gold star today.

Jonathan Perlin – Hospital Corporation of America – CMO & President
On Wednesday's blog. I'm just kidding.

M
Two comments, really. One is, I think it was striking to hear from Paul Tang about the process going on in the Policy Committee. Then look at your long list, because in fact what we saw there was that there were a few things that were prioritized by public comment as being very clear high priorities with a lot of support and other things that had mixed reviews or actually weren't on the list. So I guess my general comment is let's make sure that we work on things that are actually going to be in the Policy Committee recommendations and not on things that are in a more expanded list that through the comment process

and prioritization may potentially drop out of stage two. So it's really about the prioritization and alignment and effective use of resources.

Then my much more specific comment is for one of things that was on the Policy Committee highly supported list that I think does not appear on your list is discharge prescriptions. Of course discharge prescriptions frequently are filled within the hospital by the hospital pharmacy using the HL-7 standards that are allowed under Medicare Modernization Part D. So I'd urge us to consider aligning our standards with those of Part D even though it's not interoperability in an inter-organizational sense, for certification it would actually be spectacularly easy to do conformance testing on that. So I think that would be a good point of alignment.

Jonathan Perlin – Hospital Corporation of America – CMO & President
And really just to emphasize Doug's slide three, which notes not only are we creating new functionality and plus five new standards, but we are reloading and refreshing the previously dictated standards. And this may be one where, oh, it was always ambulatory and now it's transitioned so it's not so much an "or" as it is a "here's a different use case." Good point. Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Thank you, Doug, and Steve. This seems to differ a bit from the guidance we've been given before, and in some ways it actually adds some clarity, like the different buckets, and in other ways it raises a couple of questions, so I want to ask a couple of questions here. In the past we've been told and our Privacy and Security Workgroup has been proceeding to recommend to the Standards and Interoperability framework specific requirements for standards and then we've been told that the S&I framework would actually develop the standards, come back to us, and we would also recommend evaluation criteria to be used in evaluating those standards. This seemed not to capture any of that at all, so I was wondering where that went. Both our presentation last month and then this month reflects that previous guidance that seems not to clearly fit into this new framework. So that's my question is, I do get that we should recommend a bucket, and if it fits in Bucket A we say, okay, X.509 is your standard, run with it. But are we still to provide requirements and evaluation criteria for Buckets B through D?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Help me understand, when you say "evaluation criteria" is it evaluation criteria of the standard?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, that's what we've been told before, that we were to provide requirements that the standard that the S&I framework would then develop should meet, and then the S&I framework would come back to this committee and say, here's our standards, what do you think? And then we would use those like we did with the Direct Project.

John Halamka – Harvard Medical School – Chief Information Officer
Let me give you a specific example. Let's pick on LDAP for a minute, because that's a good one, which is to say we cannot come up with one canonical recommendation for provider directory query because there doesn't appear to be any standards that meet all the criteria we think it should have. So, Doug, do you want three of us to get together and come up with a specification for a new restful protocol that does what we need? Or do you want us to write a series of what we think are characteristics that would be ideal of such a protocol and then hand it off to you, where the S&I framework would then come back with an answer to us?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think one of the things that we—and this goes back to, John, your point earlier about HITSP. Where that fits is that HITSP in the past was constrained to say what's out there and if I have to go from Point A to Point C, and there's no real clear way of getting all those standards. You cobble together all the pieces so that you can, in a circuitous way, accomplish the task, one would hope that within the S&I framework if there's an easy way to get from A to B and you just need to build the B in between, the S&I framework can I think help us do that. But at the same time if there's an existing standard, and this goes back to maybe it was Carol's point that was made, that we shouldn't reinvent the wheel. If there is something out

there that we think is going to serve our purposes, like LDAP, we can say that we think this is the right approach or the right standard that we should use for directories. But we don't have an implementation guide for that just yet. Maybe that's something that the S&I framework can help us get to.

Now, we might say, and we've done this in meaningful use stage one, where we adopted a standard saying we think everybody should use this particular standard, but we haven't adopted an implementation guide and it makes it harder for us I think to test and get the certification criteria. We have a tremendous amount of work that we need to do. The Direct Project took us about 12 to 15 months to really get to the point where we had the actual use and the pilots and the other things in place. We don't have the luxury this summer to do all of those things. We all have to go back to school in September and camp is over, and so we have to figure out what we can accomplish in that time frame. So what I want us to be able to think about well, how can we get as much of the work done over the summer and to focus the energies within the S&I framework on those things that really fall into Bucket C. So we have a standard, we're pretty close to where we need to go, but we need some consensus in the industry or within the community to figure out what's the data model look like in LDAP that we think will allow us to have interoperability across different directories. Or, what are the extensions that we need within the X.509 standard that will allow the certificates to have the right information across that?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
That's what we recommended to you before. That's exactly what we—

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Right, and that's why—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
That was the right kind of recommendation. Here's 509, but you S&I framework need to name the data elements that go into the certificate.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think that's something that we can accomplish. Now, if what we say is that we need to, I'm just going to pick on, what shall I pick on, family history, I know that there's a standard out there around family history, but we say there is not a standard for a particular function. We think it's an important function and we want to start with a blank sheet of paper, or we've got multiple ways of doing this. We want to come to some convergence, that may be something that falls into bucket D that says we think it's really important for meaningful use stage three, we think it's going to take us more than six months to get there. Let's start that process and see if we can't move things along with the planning and getting things organized without necessarily saying we need to do a huge crash to try to get some work done between now and, say, August or September.

The other thing is that it may be that there's a really good implementation guide out there that we just feel like there's a few things that we'd like to get some more feedback on. There's no reason why we couldn't post that without starting an initiative, but to post that and provide a way of getting feedback on a Wiki that we then accumulate that, we organize that, and then we summarize what that information looks like. I just think that for us to be successful in getting our work done, we have to use every tool in our tool kit. So it's going to include the S&I framework, it's going to include using federal register, and it may be that we find that a hearing is the right way to help us with that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I was just trying to figure out ..., but I do have one more comment about Bucket C, two comments about Bucket C. Number one is that there are instances, and I can give you a specific example, there will be also instances where what the Policy Committee hands over to us doesn't fit ideally, exactly, precisely within a standard. So it's not just you have existing standards, no implementation guide, but there's also the case where there's an existing standard but it is not consistent with the policy prescribed by the Policy Committee. I'll give you an example, the tiger team recommended for two factor authentication NIST level three authentication, but allowing for biometric to be one of the two factors, and NIST level three

doesn't allow that. So there are also cases where there are policy influences that come into play and I think that Bucket C is where you accommodate those.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes, and I think that's an important point. That's, I think, one of the reasons it's so important early in this process to make sure that the standards community and the policy community are talking. Because you may go back and say, listen, if you want us to take this policy objective and move it forward, there's a lot of work that needs to be done because we don't have a standard that really fits into that objective very clearly. So do we then delay the implementation of that policy objective until we get the perfect standard to support that? Do we modify the policy objectives to get us started? Do we create an incremental path that says we're going to get started here and then we want to do some additional work? But that's, I think, what's so critical about having that dialogue between what's the technology and standards to support this, and how to work with the policy to make sure that we're aligned really well.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Another comment about that same thing is that on one of these—on slide four, I think it was—you had the tiger team providing an implementation guide, that whole column in fact relating to Chris' comment earlier. I think we need a definition of what an implementation guide is, because I agree with Chris, that value set is not an implementation guide and nor is a tiger team recommendation an implementation guide. So I think if we're going to recommend those we need to know what it is we're recommending.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
And I'll just another finer point on what Chris has articulated, is that what you want is you want all the things that will make people successful in achieving the goals of interoperability. Without having explicit value sets defined, I don't think we're going to be able to get there. So even though I pulled out vocabularies in August, I did it more for emphasis because I didn't want it to be a sub, sub-bullet of one of these things and see as if it doesn't have the import that we need. When I think about the work that we need to do within interoperability across the healthcare domain, we can turn to people in other industries and to NIST to help us with security and authentication, because we shouldn't come up with healthcare specific ways of doing that. We should really leverage things that are across the industry. But there's no one, apart from the healthcare folks, who are going to be able to really spend the concerted effort on vocabularies and value sets. That is what truly defines health information exchange. So we have to make sure that we address that and we get an incremental path that gets us started and can grow, because we can't turn to other sectors of the economy or of industry to help us solve the very specific problems that we have around vocabulary and terminology within healthcare.

John Halamka – Harvard Medical School – Chief Information Officer
To summarize all of this, Dixie, we're going to do our very best to identify the canonical standards that will just work. But if we can't then we will do our best to pick as many of the standards we think that will work and specify characteristics of what we need additional to them, recognizing we have minimal resources between now and September in the S&I framework to boil the ocean, and we'll do our best. As you say, if we can't get there because the standards don't exist, well then there may need to be reflection on what policy goals we have in the short term.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It sounds like he's saying implementation guide is really implementation guidance; anything you can put into that to help them.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think there's a range. To Chris' point, if you make the value sets part of the standard, that's actually a much stronger approach than if you make it part of an implementation guide or implementation guidance. We have that whole continuum, and you may say, you know what, we're not quite certain exactly what's the right thing to do, and it becomes guidance. We're pretty clear about it. It's a guide. We know that this is the right approach, or we think that this is the way that we're going to achieve our goal, make it part of the standard.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great. David McCallie, and is that Elizabeth Holland or Walter Suarez?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
....

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Doug, a question for you, to run with the camp metaphor maybe too far, who's the cabin counselor or who's the camp director this summer calling the shots on these things? It's really an elaboration of Dixie's question. So each of these bullet points up here could take the form of a project similar to three that you already have active in the externally exposed aspects of the S&I framework, where you have a list of community volunteers and a Wiki that tracks activity. It's very open and public and it seems to be working well, or these things are things that would have in the past perhaps been tasked to a workgroup of this committee for deliberation and recommendation. Is it going to be all of the above, a mix of the above? Who's in charge, I guess, is the question? Who's the camp counselor?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
I think it's going to require a concerted effort across that. There may be some things for which we have a pretty good sense about where things need to go and we can have some working groups that are going to be focused on some of those issues. We can leverage all of the activities within the S&I framework. One of the things that I think we realize is that the Standards and Interoperability framework is most successful when there are clear goals, clear objectives, measurable outcomes, and an evangelist who can make sure that they hold everybody's feet to the fire to achieve those goals. Those people are hard to find sometimes and we need to try to do our very, very best to not let, in some sense, perfect be the enemy of good. And even in the work that we do around the S&I framework, it may be the perfect solution would be for us to identify a key evangelist and to drive an S&I framework initiative. We may not have either the people identified or the resources to do that. We may say we'll have a couple of working groups, maybe we hold a hearing, we post our recommendations to a Wiki within the S&I framework, we get some of those results back, and then we proceed with our best goals.

Part of the stuff that Steve had presented earlier is that we will be working within ONC to help provide that camp counselor triage, if you will, that we hope will help provide some of that guidance as well. Quite frankly, I wanted to, over the course of the last week or so, to get something out there for people to react to. In some of these circumstances, I think we do need to probably spend some additional time going through this and saying which is it that we need to create a working group. What is it that needs to go in to the S&I framework as an initiative, realizing that we have a limited number of months to be able to do the work that needs to be done. How can we leverage the current work and maybe take lab or transitions of care or one of those things and figure out a way in which we can leverage that. We should be having ongoing in all of those initiatives discussions around vocabularies and terminologies and the value sets that are going to happen in transitions of care and the lab results. But to answer your question, I think within ONC we will be having some probably weekly or biweekly meetings in which we will be helping to triage that and then communicating with this group and with the working groups to make sure that we're on track with what it is that we need to accomplish.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
That sounds good. It's, I suspect, still a little bit mysterious as to how it actually plays out. Some of these things are fairly sensitive or political, if you would, issues. They have big implications. Even changing from CDA to green CDA could have a profound impact on vendor effort required, not to mention other things. It's just unclear to me still what the process is. Is it he who yells loudest in the S&I Wiki, or is it a formal process where a workgroup of Standards Committee makes a decision and says we've considered your recommendations and we agree with this or we want to override this? You recall the CCR, CCD issues that we wrestled with in round one, every one of these has a parallel issue out there lurking somewhere I'm sure, even something seemingly as innocuous as LVAP versus made up new restful API. Those are profound issues and I'm just not clear on how it plays out. I like what you're trying to do and I like the planning ahead and surfacing the issues up front, I commend you for that. It's just unclear. I don't need an answer now. I think we're all a little unclear how it unfurls over the summer. It's just ....

John Halamka – Harvard Medical School – Chief Information Officer
Presumably, again, we will be assigned work, and between now and the next meeting there are going to have to be phone calls to make sure that work assignment is crisp. As we begin deliberations on specific work assignments and provide input to the S&I framework where necessary and the S&I framework has deliberations, and then feeds back to us the results of their deliberations for our comment. Then ultimately the regulation comes out, based on whatever final recommendations we make, and it's up to you guys to take all input from all sources and put it into meaningful and thoughtful regulation. I think that's how the process works.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes, and I think we will continue to refine the summer camp agenda with all of this and try to figure out what's the right tool for us to be able to get this taken care of. This isn't something then that we, again, I think, need to be able to present this information, organize it, get feedback and comments from folks. My goal here was not to present a blank sheet of paper, but to actually start that conversation. One of the first things that we need to do between May and June here is to review the summer work plan. That was a bullet that basically was to say, take the feedback from this conversation to flow it back in to coming up with an updated work list to work with the chairs in the various committees to make sure that we've got the right allocation of work. And then to set up what the work plan looks like and what are the deadlines for when we want to get the deliverables back.

Jonathan Perlin – Hospital Corporation of America – CMO & President
... for me, certificate interoperability, I think we're in good shape. We'll hear more in May about directories, so that's naturally going to be there. Longitudinal care plans we may not actually want high on the agenda if per Paul's comments it's actually going to be an item deferred out of stage two. Then there may be some low hanging fruit like in the NCPDP world and the drug prescribing standards or the things Jamie mentioned that they're just obvious, and we can include those. It's just a statement that we all agree. I know we're running very short on time, so the last two comments, Walter and of course Wes has his card up on the phone.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Very briefly, I'm beginning to like this summer camp concept. But before I enroll, I just wanted to understand—

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
You're already enrolled.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Oh, okay. I wanted to understand the expectation and the "What I did this summer" review part. There's been a lot of talk, between Dixie and David's comments, about how do we process all these, and the slide, the title actually says, "Review Standards," it doesn't say "Recommend Standards." So the question at the bottom of the pile really is, at what point after we go through summer camp will we come out from the Standards Committee with the recommendations on all the standards for all these different items? I presume perhaps that some of them we can come up with fairly quickly, some of them we might need to work in a fall camp or a winter camp or whatever, over the next few months after summer. So I think that might help understand the expectations of what we will be doing during the summer camp really is, at the end of the summer camp we're going to write 15 letters with recommendations on the standards, or are we going to provide feedback in the review. I think, John, you weave very nicely sort of the Policy Committee, Standards Committee, S&I framework, Standards Committee comes back and reviews the recommendations, so that kind of sequence I'm not sure if we're going to be able to do it during the summer. But I just wanted to understand the expectations from that summer camp and outcomes and the recommendations ....

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
As soon as you define success for something, I think we would love to have recommendations on an incremental basis, not to hold them to the end of the summer where you have the comprehensive kind of

book report. So to the degree that there are low hanging fruit that we currently have available, doing a refresh and reload of currently adopted certification criteria anything that we think has a lot of interest behind it for meaningful use stage two. Looking at those areas that can clearly be improved, that we already have and that are known quantities, if you're ready by the next meeting to make recommendations, that would be great. The sooner the better from us in terms of writing and drafting the rules, and in terms of proposals, where we have greater certainty, in terms of what the recommendations are and how we need to draft the rules, it greatly expedites our processes. As you look at reviewing the work plan, and I think as John mentioned earlier, strategically ordering certain things to really nail down your sequence, I could foresee you all making recommendations on an incremental basis every month until the end of August, looking at what needs the most time for discussion and chipping away at the things that are ....

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
But would the expectation be that the end of August is the last time when recommendations can be made, because some of these things are tough things that could take until December or November.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Sure, and I think that's some of the calculus that would play into a recommendation to inform a policy decision, whether or not it's included, or if we go to more of a functional capability versus the interoperable capability. Some of the Feds or former Feds know a lot of clearance processes involved in getting the regulations out, so we already have a backwards plan for when we need to have something submitted to HHS clearance and then to get it to ONC and then eventually getting a rule published. So backing all of those dates up, we're kind of on the same timeline that we were on two years ago, about getting recommendations that we can run with by the end of the summer. You'll have an opportunity to comment on the proposed rule, obviously, once things get done going through the rule making process, but at that point in time it will be more difficult to introduce something new.

John Halamka – Harvard Medical School – Chief Information Officer
... we really want to get these work assignments out as quickly as we can, so we should set up some calls to get that done expeditiously.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Just one more point, I had an earlier question that John, who we postponed to this, I suppose it was this panel, right? Because the earlier question was really not, I'm not thinking about what I did this summer, but next summer what I did during the last year. In other words, you talk about the regulatory process, and my question earlier was about the compressed time frame that we have for the development of the meaningful use stage two and standards and certification criteria, and then the compressed time after that to jump in and start the implementation of those. I just wanted to hear your perspectives on that, because as I mentioned earlier, in stage one we actually had, up until basically, I think it's going to be September 30th of this year, because the last reporting period could be the last quarter of this year. So we had up to 14 months after the actual final regulations were published, and in this case we might be compressed to maybe 6 months at the most. So any comments on that or review—

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
We're very aware of all of the timing suggestions and concerns that people have brought up and have been in active consideration, the Meaningful Use Workgroup has been considering different options in their discussions and we also have meetings between ONC and CMS to best figure out what's going to be the appropriate balance. I think everything is on the table right now in terms of options to hear about, we want everyone's best ideas, and then we're going to have to look in terms of, again, what the outcomes are that we're looking for and how to best achieve those with the timing constrains we have. We know that there are real world challenges to, especially some of the new objectives and measures that are being considered and how to best balance those challenges. There are a lot of trade-offs involved, especially with all of the other great activities that are coming out of the Affordable Care Act.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Wes, you have the last word, very briefly.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay. I just wanted to say that Doug at ONC has been working on setting this S&I framework for, it seems like years now, and we are now beginning to transition to using it. This is putting us back into an uncomfortable state we were in a year ago or a year and a half ago as a committee, which is where we don't have any intuition or any experience based on how things are going to work. So we'll be looking for Doug to have a clipboard and a great big whistle at summer camp.

I think that the most encouraging thing I heard today, and what I hope to see demonstrated quickly, is a process by which the need for and feasibility of producing standards or, let's call it, specifications, for lack of a better word, is factored into the policy decisions in terms of meaningful use stages. I certainly hope that the implementation group will be working with priority on those issues. There was a long dialogue between Chris and Doug about what's a standard and what's an implementation guide and the relationship of that to vocabulary standards. I'd like to suggest that in the interest of priority setting in the way that we've been talking about it, that we assume that anything that is produced through an SDO like consensus process will have ambiguities and be fitted to a broader community than what can be used as a testing basis for certification. So unless it's proven otherwise, there's a need for an ancillary specification.

I think it's important to recognize that vocabularies aren't a plug-in. Yu can't say here's a field, either use SNOMED or use ICD-10 in this field. That's not a sensible statement, but to the extent that value sets represent a restriction on the use of a code set if we're talking about physical injuries, we're only interested in certain axes of SNOMED or something like that. Then that is often a kind of addition that's applied to a standard after the fact, rather than as part of the standards process.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you very much, Wes. I'd like to wrap up this discussion. It's clear that we will have to refine the assignments and get the assignments out and hopefully by May we will both have a crisp list of the work ahead but also some pre-work on some of the things that are obvious as we go forward to these next few months ahead.

Now we're going to move very rapidly to Paul Egerman. I will give a 30 second summary of what Jamie would have said should he have been here, that there have been four calls of the Vocabulary Taskforce, they've been thinking about what are the appropriate next steps to accelerate the use of vocabularies and the creation of tools. For example, suggesting that there is a single vocabulary per purpose, rather than to Doug's point about you say, oh, you have five choices of vocabularies for a singular purpose, lab. This gets to be extraordinarily confusing and creates mapping that goes on forever, so single vocabulary per purpose, and where there do need to be cross-maps among vocabularies, create those. Where there are value sets and subsets that will accelerate all of our work, and to Wes' comment about ensuring those are incorporated into the standards or easily used within the context of a standard, they would like to articulate which are the appropriate meaningful subsets and how they can be easily made available. So he'll provide much more detail in the next meeting.

With that, Paul.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Just one question, this is David McCallie, about the vocabularies and John Klimek maybe you can weigh in on this. I understand that NCPDP has a taskforce running on allergies and my question is, is that helping you specify the allergy profile, which is left hanging, is that work getting fed into Jamie's group

John Klimek – NCPDP – VP Industry Information Technology
Right.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
So there is a connection there?

John Klimek – NCPDP – VP Industry Information Technology
Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Great, I just wanted to make sure it wasn't lost. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I appreciate the robust discussion about not only the subject of our work but the structure of our work as it goes forward. I think the conversation demonstrates how mightily complex it is, a number of the dimensions, the complexity has been drawn out today. One of the challenges that they expect ... discussion during setup of today's meeting was that we were simultaneously describing the fundamental properties and the use of those fundamental properties for activities that are more emergent. We're trying to do both simultaneously, and so recognize the hierarchical nature of certain activities, yet at the same time I think it was well described that there is a timeline in the set of activities that has to occur as well.

I think that complexity is also a parallel and one that we appreciate Paul Egerman's terrific leadership, in bringing to us a synthesis of the recommendations of the PCAST Report that is wonderfully aspirational in terms of what it takes. It's taking us back to the earlier conversations here about building better healthcare and the ability to bring together the PCAST recommendations in a way that the vehicle of the process that's been identified, in fact, in law, to accelerate health information technology can incorporate those aspirations and move forward. It's a terrific discussion. I've admired Paul Egerman's leadership of the PCAST Workgroup, along with Bill Stead, because that simultaneous complexity of things that one aspires to and the fundamental elements that would make that possible is one of the core discussions. Obviously there's intersection very closely with the work of the Standards group in terms of supporting both the foundational elements and the emerging properties of more effective healthcare systems. John, anything you want to add as we—

John Halamka – Harvard Medical School – Chief Information Officer
Again, Paul, thanks so much for your leadership because you've taken a very complex topic with a lot of controversy and given us, I think, a clear set of next steps. We'll also hear from Doug as to some pre-work he's done to supplement the workgroup's report that Paul will describe.

Paul Egerman – Software Entrepreneur
Thank you. I appreciate those kind comments from John and Jonathan. In fact, those comments were so kind I almost think I shouldn't say anything because I can only make things worse by talking based on those comments. But I am Paul Egerman. I'm here to discuss a brief summary of the PCAST Report Workgroup. To briefly review for everybody, PCAST is the President's Council of Advisors on Science and Technology and it is an advisory group, just like the HIT Standards Committee. Just like your group it gives advice to the president, and President Obama did read the report. The report was issued December 8, 2010 and based on advice that he received from Aneesh Chopra and the Office of Science and Technology, felt that this was the right direction for this country.

We had a workgroup that was formed in January, worked very hard over a fairly short period of time, and what you see on your screen and what's in your notes is the workgroup's charge. If you look at this charge you see those kinds of words like "to assist ONC to synthesize and analyze public comments, discuss the implications, elaborate on the recommendations and how they can be integrated into the strategic framework." So you look at these words "assist," "analyze," and "discuss," what you don't see in our workgroup charge anywhere is the word "judge." Our job was not in any way to judge the PCAST Report, so that's not what I'm here to talk about. That's not the way our letter should be interpreted. In fact, it's very important that if you read our letter or you listen to my comments that nothing in the letter and nothing I say should be interpreted as either endorsing or rejecting the technology or endorsing or rejecting any of the policy concepts that might be inferred from the PCAST Report.

This is a list of the terrific members of the group, and this was a great group of people. My co-chair, Bill Stead, unfortunately is unable to make this meeting, but we do have present a number of the members of the workgroup. I do want to acknowledge that Dixie Baker, Jonathan Perlin, John Halamka, Steve Ondra,

and also on the phone Wes Rishel, all did terrific work contributing to this letter, which turned out to be 45 pages long. I would tell you that nearly every member of the workgroup wrote a section of that letter, and nearly every member of the workgroup also provided a near microscopic review of the words in that letter, so it was carefully reviewed, which was very much appreciated. So those are our workgroup members. I also want to quickly acknowledge, we had significant support from ONC, Doug Fridsma, Jodi Daniel, Jamie Skipper, and the always extraordinary Judy Sparrow, of course who was extremely helpful in this entire process, and from PCAST of course Christine Cassel, Craig Mundie, and Bill Press. We were greatly influenced by public comments and happened to see behind the audience Mark Segal, who also provides some very important input, so I want to say thank you for your input, Mark, and for everybody who provided public comments.

The PCAST Report, there's a slide that has three major directions. I happened to notice that Doug, who is presenting after me, has the same slide in his deck, and I don't know if that's like a copyright infringement or something, but these are the three major directions from the report. To, again, quickly review this, the first one is—

W
....

Paul Egerman – Software Entrepreneur
I'm sorry, did somebody say something?

M
It was on the line.

Paul Egerman – Software Entrepreneur
The first comment was to accelerate progress. I think a clear theme of the PCAST Report is a call to action. It says accelerate progress to act boldly, to act urgently. The second major direction that we saw was these three words that are underlined, the "New Exchange Architecture," and then there's a lot of words after that, universal exchange language, interlink search capabilities, but the new exchange architecture. We underlined that because we want to make it clear that at least in our reading of the PCAST Report this was not just a report that said information exchange is good and people should exchange information, it went further than that. It basically describes a specific architecture for that exchange, and in some sense this does represent a change in direction for ONC, because ONC in the past has been saying let 1,000 flowers bloom and now we have a new exchange architecture, so I guess we can say we have a flower pot with 1,000 flowers blooming.

The third major direction is basically this is an evolutionary transition, we underline the word "evolutionary." Nobody should be concerned that this is a rip and replace situation. In describing these three major directions I also want to be clear that the PCAST Report and this new exchange architecture is not intended to be a complete description for everything that happens in information exchange. If you think about information exchange you can think of it in the form of a series of building blocks or tools or tool kits and the new exchange architecture is sort of like one set of tool kits for a certain purpose, that there are other purposes that it does not cover. There was also a reason why we call it the new exchange architecture and not the PCAST architecture, and I'll come to that in a minute.

We divided our workgroup into, at one point, two taskforces. There was one taskforce that dealt with policy issues, another taskforce that dealt with some implementation and technology issues. On the policy side what we tried to do was to do what we call policy spotting, to actually spot and say where there were policy issues and not attempt to resolve any of those policy issues. I might tell you it's a lot more fun to simply give a laundry list to ONC and say, yes, you've got to solve all these policy problems, as opposed to try to figure out how they're supposed to solve them. So we produced that list. These were the top three, there's at least in the letter, at least another dozen more very interesting issues. It's an interesting discussion.

The first one, of course, is privacy and security, and that shouldn't be a surprise to anybody. In any information exchange endeavor privacy is going to be a significant and major policy issue and we listed out what the specific issues that people were concerned about. A lot of it had to do with the granularity potentially, the practicality of granularity of choice was also spotlighted as a privacy issue. The second issue is called multi-patient, multi-entity analysis. That's also sort of a mouthful. That is sometimes also called secondary uses of data, so I guess secondary uses turned out to be number two. But basically there's a very interesting discussion here about the relationship between the secondary uses and the primary or clinical uses of the data and to what extent one should be influencing the other and the impact that that has on the policy issues. Then there were significant governance issues that were raised, especially related to this concept of this entity called the DEAS, the "Deas" or the "Deese," I'm not quite sure what the standard is for pronouncing it. I understand ONC is going with "Deese," but I'm not sure that they've gotten advice on that pronunciation.

These were the highlights of the policy issues. We did discover that all policy issues were interrelated, as were all the technology issues, and the policy and the technology issues were related to each other. The letter has a great description of the technology itself and it has in that this overview of the data flow that has these four boxes. I have to use this laser pointer because somehow Doug Fridsma carries a laser pointer with him everywhere and he gave this to me to use and I feel compelled, I have to use this thing. Anyway, you have these four boxes, so the first box says "data providers" and one way to think of what's in that box is ... like the EHR systems. The second box has all this information in it. It has the health data, metadata. I view that box ... as the data abstraction layer. It's a layer of data and related information that actually still exists within the four walls of the healthcare provider. It's the kinds of concepts that middleware recommended in the report would be used to layer on top of the EHR system.

I'm going to skip the third box for a minute. The fourth box is data users, data users being presumably predominantly clinicians who are able to do inquiries. Basically the image is to be able to inquire into basically every EHR system in effect in the country on any single patient, and to do that as easily as one might do an Internet search using Google or Bing or some search engine to be able to find information.

The third box is external to the healthcare provider and it has this thing called a DEAS, the Data Element Access Service. It has all kinds of indexing and other capabilities. And my own personal nickname for the third box was that this was Pandora's box, and the reason I called it that was when you looked at the thorniest policy issues that we had and the most complicated technology issues, they all were in that one area. I don't want to say "all," but the major portion, 80% of it seemed to be in that area. That was the most difficult process. So I point this out to this group since you will end up making recommendations to implement these issues that there is a need to think outside of this box and to think about ways to—if there are ways that you could implement the systems, there's less information that is externalized, in terms of metadata indexing that helps to mitigate some of the policy and the technical issues. If there is a way to actually eliminate this box entirely that would also be something that would completely change some of the policy and technical issues.

So that's a comment about the data flow. The implementation team, influenced by some of the policy issues, looked at four use cases for the system, and these use cases were intended to be progressive in terms of how they impacted all of the basic policy challenges. The first one is a push by patient between two points, the idea being is that if the patient is pushing data that is a way to skip around, or at least minimize some of these privacy issues because it's being done at the direction of the patient. A simple search was intended to be a way to do a search, unlike a CCD or a CCR, a summary so you can hopefully minimize some of the concerns about granularity. A complex search is now, once you get to that point you have to deal with a fair amount of complexity and certainly the four use cases you also have to deal with a fair amount of complexity.

Then in the letter there is this really nice table, it lists a segment of the table, it's not a complete description, but the purpose of this is to simply show that there's a possible progression, that's one of the things that was learned. The columns, you see level one, level two, level three, and the columns were related to the different use cases and the rows, there were 15 basic components that were decided that were implementation components. What the implementation team showed is that you can start with the

more fundamental concepts of push by patient and proceed to the more complicated ones and you weren't throwing away the work you had done previously because you could proceed through this process and resolve these issues as you proceeded, so it was a concept of the progression.

We did not make specific recommendations, but we just described a few alternatives that ONC might consider for stage two of meaningful use. This was presented to the Policy Committee last week and the first alternative was this concept that there might be a patient portal so that patients could have access to their EHR data and then that patients could directly download that data using the universal exchange language. But they could download it and then if they wanted to they could subsequently upload it to a PHR system, or alternatively they could, through the portal, request that their data be transmitted directly from the provider to perhaps a PHR system.

We defined the implementation steps. The implementation steps were intended—we call this version zero of the universal exchange language, but these steps were intended to be done in such a way that in effect there was, I don't know if I'm using the right terminology, like a wrapper placed around a CCD or a CCR. That you would treat the CCD and CCR almost as if it itself were a single data element and so that you would put the universal exchange language wrapper around this as a way in order to get starred. This alternative does not require tagging each individual data element, although I know they're already tagged within the CCD and the CCR, so we show those implementation steps.

Then the second alternative that we provided for meaningful use stage two was simply to provide certification criteria for other exchange transactions. If there's appropriate exchange transactions that would also be a vehicle for beginning to implement this new exchange architecture. We provide these concepts because we were asking in response to the call to action in the first directive, the call to action in the PCAST Report in terms of what we felt we could get done. The consensus of the workgroup was that we could not proceed past that first use case, however. We looked at the simple search, which is just a basic look up of a patient's CCD or CCR and the belief was in the time frame involved in terms of the kinds of policy issues that were involved we could not get that done in time for stage two. So that was the direction of the workgroup.

I'm going through this very quickly because, as I say, there are so many members that overlap, but here is a summary of our workgroup's efforts. The workgroup is a diverse group of people and I made that comment about endorsing and rejecting the technology and I would say within the workgroup as we proceeded different people did make their own judgments about the PCAST Report and we had a range of views about that issue. However, we had complete consensus about these three sentences in terms of our summary and these are important concepts.

The first one is to say the PCAST Report describes a national use advanced technology and it's a compelling vision. The second statement that's very important is to realize what it says here, that there are major policy and operational feasibility concerns with proposed technology. Particularly, it's important to realize we are commenting on a report. This is a concept, that's what we're talking about. And then the third concept is also very important. It says aggressive and rapid progress is possible only with an incremental test bed approach, that we need large operational tests to resolve the policy and feasibility concerns. So exactly as Jonathan said before, the fundamental challenge that ONC has is on the one hand to balance the aspirational goals with somewhat inspirational comments made in the PCAST Report with, on the other hand, sort of pragmatic issues of what's involved in implementing on a nationwide basis in the EHR system. Especially when I think about the discussions we heard this morning, where there are so many interesting detailed issues, and so that's the ultimate challenge. That's the report. I don't know if any members of the workgroup have anything they want to add.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you for really thoughtful comments. I'm going to suggest that we take Doug's presentation or synthesis of, and that was just an incredible synthesis, many of you who have either participated directly or listened in to the PCAST to summarize so succinctly and thoughtfully is quite remarkable. Let's make sure that our next set of conversations ... by what we can know about the analysis of existing metadata

standards that MITRE provided to Doug, so let's take that and then come back and integrate our questions. So we're going to Doug Fridsma.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Thank you, Paul. Again, I'll just echo the comments about just the remarkable leadership that Paul demonstrated as part of this particular project and how grateful we are for the work that you've been doing with this particular committee. Obviously we've been involved, ONC has been involved, and we got our chance to see as the group began to converge on some recommendations. If you take a look at the two different alternatives that Paul took a look at, we wanted to move rapidly and be responsive to that first charge, which was to accelerate progress towards this robust change of health information. So probably about two weeks ago or so, maybe it was a little bit longer than that, we reached out to the team from MITRE that has been doing tremendously good work, both with regard to some of the quality measure analysis and the like, and we gave them a charge. We asked them to help us accelerate the progress towards getting some standards or getting some identification of the things that we might need to implement the PCAST vision.

One of the things that came out of that report is that there are a couple of metadata element categories that were going to be fundamental across what we wanted to accomplish, or what the recommendations that were coming out of the working group. That included metadata around patient matching, clearly we would need to be able to identify a patient and being able to identify what the data was and what was important about that data. So if you got data from multiple sources we could collect that and merge it together. We needed something about provenance, the who, what, where, why about the data information, so if it was a test who ordered it, where did it come from, what kind of test it was, that sort of thing, and then something about granular consent. And realizing that privacy and security were really important we wanted to make sure that we tried to take a look at those particular things.

What we charged the team to go with—and there's a napkin floating around in MITRE some place that has my scribbles on it in terms of what we wanted them to try to accomplish—what we asked them to do was to take a look at a series of standards that were out there. Because if you remember, we wanted to establish an evolutionary transition path, so one way to do that is to take a look at what we have now, that's also a good way to accelerate, and figure out how that fit into these metadata element categories around patient match, provenance, and consent.

So this is very high level. This is not something that has had a lot of detailed analysis on it. What we did is we categorized, and I'll show you these charts as we go through this, "No," or "N" means that we didn't have a corresponding element. It doesn't mean that there weren't some things that might have been close or whatever, but our rough assessment was that a particular set of standards didn't include that particular element. A "Y" indicated that we believe that that particular standard had some elements that were consistent with or similar to the metadata element around patient matching provenance and consent. It's important to put a caveat on this, is that we also included whether there were optional elements. So if it was an optional element was it required for the standard? We put a yes there. We also did not evaluate syntax, semantic, or structural requirements. So if somebody said patient name, we didn't go deeper and say, well, how did they represent it? What's the syntax around that? If somebody put in something around consent or the like we didn't say well, what did they mean by that? Did they have the common elements? In large part this is, again, an effort to accelerate the work that we have to do over the summer and to try to be responsive to the PCAST vision to move things forward quickly.

With regard to patient matching, the goal here is to find all of a patient's tagged data elements and multiple DEAS' and we can argue a little bit about what the structure might look like, but this is just to frame the questions that we had. If you wanted to get data on John Smith you would try to go someplace to get that information and you might get that information through a DEAS, there might be multiple ones of those, it might be that there's a singular one and you're trying to get this information from the various hospitals or clinics that might have it. From one you might get no results. From another it might be John Smith with a particular date of birth represented as 5-12-48. Another might be Jonathan Smith with a date of birth of 05-12-1948.

So part of the challenges that we have when you think about patient matching is that there's a bias towards false negatives, in the sense that you would rather have a false negative than a false positive that would associate the wrong information with the patient. There's a lot of challenges and differences between naming structure between different cultures and the way in which that's represented. We recognize that there's a time sensitivity of names and addresses, because names can change when people get married or the like, and that addresses, particularly if we're using current addresses, might change. While Social Security number is a good identifier, there's a tremendous number of issues around that that would be challenging. In fact, a lot of this work was based on a RAND study to take a look at patient matching, and there's some additional supplemental information not presented here that was included as part of the MITRE analysis. The goal here is to suppose a subset of patient data that maximizes relevance and completeness of the information that's returned with a bias towards tolerating false negatives and not wanting to have false positives.

If you take a look at that and take a look at a whole series of different standards that might be out there, HL-7 version 2, CDA header, IAG, XDS, metadata, CCR, NIEM, as well as the Google CCR. Then take a look at the five elements that RAND had recommended as being helpful with patient match, nearly all of them had something around a patient ID, a patient name, a date of birth, address, and zip code. So that tells us that a lot of the existing standards out there incorporate that. Now, obviously there are syntax issues and there are semantic issues and other things that we would need to consider, but it was encouraging to say that many of the standards out there have these things as part of either an optional set of elements or as something that is required.

We also wanted to take a look at provenance. So with provenance the goal here was to determine the ho, what, why, where and how of the tagged data elements. The idea here is that you would want to know, for example, if somebody got an MRI of the skull, you'd want to know it was ordered by Dr. Smith on 2-12-11, it was performed at a particular hospital on the 14th, and that the information and the results of that were transferred to the PCP, Dr. Jones, at 2-15-2011. And there might be some information that would then be associated with that.

There are other ways that you can capture provenance as well. You could say this came from a particular document. It's a subsection that we've extracted to do a particular purpose, but I think that was the basic high level use case to look at. There are challenges with this. The tagged data element versus the content provenance and how deep do you go with how you collect that stuff. Many health IT standards have pieces of the provenance information but they don't oftentimes capture that complete picture. Full provenance for a tagged data element is unlikely to be populated and it may be very expensive to maintain. You can imagine that information as it progresses through the healthcare system, if what we need to do is for each of those data elements put everything about the provenance and keep pulling that through as it moves and transitions to the healthcare environment. It could be very challenging. So we have to work through those things. The team from MITRE recommended and approached this problem with this notion of shallow provenance that might increase over time, trying to make sure that it doesn't go too deep but at least you've got some information. That perhaps as we learn more about this and do more we can add to the depths and the complexity of how the provenance might be collected.

There's a whole series of different standards that are listed. I'm going to go to my other sheet here, because I'm not sure I can read that from here. If you take a look, I think the thing that's important is that they've got a whole series of things. There's a tagged data element there that's a reference to that particular identifier for the tagged data element. There's this notion of a chain of custody for the actor, chain of custody for the affiliation, there's a chain of custody for the event that may have occurred, and some time stamp that will help with that. There may be some endpoint for some things that may be relevant to and include equipment, what was the test equipment that that laboratory test was performed on, and then one can think about a chain of custody that is recursive, that you might actually have contained within that chain of custody another whole chain. That's the way that you would link together multiple chains, if you will. Then the context, if you think about provenance, provenance is all about trying to understand the context about the data that's incorporated.

We looked at a whole series of different provenance standards there, and I'm not going to go through all of those, but we looked at CDISC and we looked at CCR and IAG profiles, NIEM, HL-7, and then a whole host of other standards that were listed. You can see that some of them did a pretty good job of collecting all of that information, and then there's some spotty coverage across this. I think it's important when you look at all of these diagrams too—I don't want to give the impression that the winner is the one that has all of the boxes filled out. But in fact what we need to do is we need to say, well maybe the way in which chain of custody is presented in, say, CDISC for these three elements are really good, but maybe the ones that we have for IAG are even better for these other ones. We might think about how we would take core metadata and take the best of breed across these different standards as well.

But it's encouraging, again, to know that there are provenance standards out there that incorporate many of these elements. This may not be the complete element list as well, but we were trying to really focus on the minimum set that we thought would help give us the information that we would need to do this. You can see it's things like the element, the actor, the affiliation, the event, the time, kind of all the things that you might have as just the minimum set that you might need to capture provenance.

When it comes to consent, this gets a little bit more challenging. We've broken this up. You can see that the use case there looks a little bit more complex as well. But the goal here is to express what tagged data elements can be shared with a party in a particular situation, so even just the goal becomes a bit more complex with things. So the challenge is conceptually you'd like to be able to say well, we want to be able to disclose "X" versus "Y," we want to protect certain kinds of information, but when you roll that into a concrete policy it gets really challenging because there's a lot of nuance that needs to be taken care of. There's the challenge of choosing the correct granularity for this, and the risk that there might be inadvertent disclosure of sensitive information. So just disclosing the existence of an HIV test, even if the results are not disclosed, or disclosing the existence of a visit to a planned parenthood clinic or to a clinic for sexually transmitted diseases could reveal information that would not want to be shared.

But if you take a look at the consent core metadata that you have there, I think the thing that's important to recognize is that there's this content metadata, the thing that might be attached to the tagged data element. Those might include things like what kind of information it is, what kind of content do we have, how sensitive is it, and is there an indication as to how this information has been obtained, the content coverage, if you will, around that.

But the thing that I think is also interesting and that the MITRE analysis pulled out, is in addition to the information that goes on there, there's a lot of additional information that you might want to know. Because you've got to be able to make sure that you release things to the right people at the right time with the right set of credentials. So you need to know something about what someone wants to use this information for so that you can make sure that that matches your policies. There may be something about their role in the organization, so the difference between releasing information for billing purposes or releasing it for clinical purposes, or if it's an emergency that information needs to be released, the affiliation, something about the credentials of the person who's requesting that information as well. I think all of those things together combined with other obligations that might need to be represented, sort of off the slide here, but these really are the policy components to this work.

I think we have just scratched the surface of some of the issues we might have around these particular data elements that look at consent, granular consent, that look at patient matching, and that look at the provenance or the context from which that information was obtained. I think the thing that is encouraging is that a lot of these things, you'll notice that there's none of those metadata elements that had a no all the way across. There was some set of standards that have at least tried to address that. That there is a way perhaps that we can take the best of breed from the existing standards that are out there, and that the list of elements is relatively constrained. We don't have a list of a thousand different kinds of metadata concepts. We've got a manageable handful for each one of those that would be helpful.

I want to make it clear that this is not the end of the analysis, this is really the beginning. We thought, again, to try to help support accelerating the conversation around this, providing something that wasn't a blank sheet of paper but trying to frame the PCAST recommendations and the metadata analysis in

existing standards that are out there along these three different areas and seeing what the minimum set that would be helpful I think is really where we're trying to go with this. So I want to acknowledge the team that worked on this. We gave them really an impossible task to basically say, take a look at the work that Paul and his team have done, take a look at these three areas, and look at all existing standards out there that could possibly apply, and make sense of it so that we can get the ball rolling. They really did that in about two weeks. I think the team is to be applauded for really being able to, I think, take a complex issue and try to create at least a starting point for our discussion. So with that, I'll turn it back over.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks. What a terrific demonstration of the interplay between the emerging properties of the system or the desired attributes of the system, and the element that constitutes that system. I know that there are a lot of questions on both aspects of that discussion. John is going to offer some framing introduction, and then we'll come around to Walter, David, and Carol.

John Halamka – Harvard Medical School – Chief Information Officer
This is just a framing comment, if I were to synthesize both Paul and Doug's presentation with just an example, so imagine that stage two has a policy measure that says it's a good idea for EHRs to share their data with PHRs. So the question we would all ask is, let's see, Google has an API, and Microsoft has an API, and Dossia has an API, and you know every one of these APIs is completely different. If this is going to be part of meaningful use, do we want to allow the thousand wildflowers to bloom, or do we say there is a consistent envelope around the payload, and the payload may be variable. It could be CCR or CCD or whatever else, it could be Blue Button, but you're going to say that the metadata will contain, who is the patient, where is this data from, and what are some specific consent of privacy flags around it?

That singular envelope is sent in a consistent fashion to each PHR vendor out there in the world and therefore that enables any EHR to wrap up content for consumption by any PHR. That would be an example of what you're calling the Universal Exchange Language stage 0. It seems like it would be a good idea and maybe even achievable. Of course there's much work to do on the metadata as you presented it, but nonetheless directionally it seems like there would be little disagreement about the desirability of taking the thousand wildflowers, allowing variation in the payload, but at least allowing the transport in the metadata around transport to be consistent.

Jonathan Perlin – Hospital Corporation of America – CMO & President
... this aspirational image, Walter—a

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes.

Jonathan Perlin – Hospital Corporation of America – CMO & President
... have robust conversation on this discussion, so Walter.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Thank you. This is great, terrific work. Thank you for providing us this. I have two comments and questions. One is on the point that Jonathan just made about the UEL version 0 and incorporating that into meaningful use stage two. It seems like the challenge that we would have is, who is really the entity that defines that standard that then can be named and adopted and incorporated into meaningful use and then incorporated into the certification process. It seems like in all the other things that we do with meaningful use, whether stage one or stage two, we're very careful in making sure that the standards selected are mature now that are in place. That they're being used. That they're being tested, and it seems like here we might be trying to push hard on getting a standard established in a version 0 form and then adopted to be incorporated into meaningful use two. So I would have a concern about that of course, so I would want perhaps reactions on your part about that.

The second comment is on the metadata part. I think the patient matching, the three that have been selected are clearly the most critical ones that we all deal with. They've been referenced in the PCAST Report. The biggest concern or biggest challenge that I saw, and a number of people saw around the PCAST Report, was this DEAS infrastructure, the entities that would become those DEAS service agencies. And so on the patient matching side this dependency on having DEAS to be the one that provides the search capability or the response capability on the metadata about patient matching is a concern. I know that this picture that is on the slide about patient matching is quite similar to what we all refer to today as the record locator service, ... entities, many places where they push out some query system that tries to locate a patient. There are interfaces outside that allow for trying to match the different individuals that could be that person that is being looked at.

I'm not sure how different that patient matching is from the record locator service today, but I don't have any issue with the provenance part. The consent of course is the big one, I suppose, because it is one that we would need to look at how much that is in place or can even be developed in time for all these. So it's really a question about across all these comments that the timing and the ability to incorporate some of this truly into meaningful use two.

Paul Egerman – Software Entrepreneur
Thank you very much, Walter. To respond to your first question about the feasibility of queries in stage two—and John Halamka did a great job of describing what the thought process was for what we call patient push. It's basically a download, what we said in the letter is if ONC chose to use the existing standards, that is used really for CCD and CCR, then we saw it as being feasible. In other words, basically if you use the same version of syntax for HML and if you use some of the CCR standards for identifying patients, then we thought this would be a useful thing and a doable thing for stage two. So that's our answer. I'll let Doug respond to the other issues.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Thank you. I think that that's an important point, that one of the things that we're trying to do, at least with this initial analysis, is trying to figure out what the down payment or what that would look like if we were going to establish a UEL and what that metadata might look like. I agree with you, I think that consent is a challenging issue. It's really an interplay between policy and technology, and that's always where the interesting things occur. But I think you can also see too that as you start to think about that it has clear implications around what information needs to be captured and associated with the tagged data element and what information needs to be captured and sent around the requestor about that. Those things all have to fit into a policy engine that's able to disambiguate the request and the data and stuff. It gets complicated pretty quickly.

I agree with you that when it comes to this patient matching, this is very similar to what has traditionally been these record locator services, and I think we need to think about that as we go forward. I think that provides us a lot of information that can accelerate the process. I think it also helps us to understand what the potential pitfalls might be, and we need to try to address those things up front as well.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Just a quick follow up. One of the most consistent comments and input back was that these are some interesting and new ideas, just not tested, so maybe one of the things that needs to be done is demonstrations testing of some of this, including, for example, this metadata on provenance and patient consent. Is that still part of the overall concept of before we mainstream this into major programs and meaningful use or some other implementations, let's do a controlled test at least, a demonstration at least of how this would work. Is that still—?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Sure. I think we will, as we go forward, we're learning a lot as people implement and they run pilots and do those sorts of things. I think we want to take an incremental approach. We want to try to accelerate the ability to exchange information. Part of the reason to do this initial analysis was to see what's out there already. What can we leverage going forward that would allow us to move more quickly? So there are pieces, there are going to be some challenging pieces, but are there pieces that have good anchors

in existing work, that can define a common set, it may be the necessary but not sufficient set, it's the core that we think everybody would agree is important. Can we, through a variety of mechanisms, through pilots, through meaningful use, all of those things, how can we then leverage this going forward. I think we're just going to have to sort some of that stuff through and if there are some things that everybody says, we're going to need this regardless of what happens in the future, those are things that we may be able to move more quickly towards meaningful use. Then those things that we really don't understand the policy implications or how all the pieces might get architected together.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Then to Wes Rishel, and also wanting to weigh in we've got David, Dixie, Carol and then we'll go to Wes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
First, thanks to both of you and to the hard working folks behind you in your committees and teams to put such a complex report into manageable bites, I'll take the liberty here to lobby a bit. I feel like we're leading the horse to water and we're also there. I really like the combination of possibilities that have been discussed that would get us to the point of where essentially the consumer could elect to become their own DEAS and manage the data that is aggregated with these wrapped metadata constraints, metadata context, that help assure that the data is what it says it is. If you use something like Direct, which is a protocol that anyone can use to send securely information from any provider's EMR to a designated aggregation point—let's call it a PHR for the time being, wrapped in the metadata standard which needs to be finished. Then let the consumer decide how that sharing occurs from there, I think that's an amazing opportunity for the future for us to build a longitudinal personal health record that essentially captures our entire medical history and makes it available.

PCAST was insightful and it opened the door to that possibility. It was also insightful that it opened the door to the understanding that search is a critical way to access that data. So summary data is really nice, but you also need to be able to look for things inside the data. If you have a lifetime record and you can't search it, it's not much use to you. So the combination of the consumer being able to aggregate that data and making it available, choosing to manage the consent, himself or herself, or designating that to a trusted entity that knows how most people want to handle consent, those combinations are really pretty powerful.

The one thing on the provenance that I didn't see mentioned—and I suspect this is a technical definition of provenance, but I think it should be woven in, Doug—is the notion of a digital signature to keep the document tamper free so that non-repudiation of authorship is a part of provenance in a way I think of in the practical sense. It may not be strictly a technical definition of provenance. But I don't know how the document got to me, but I also ought to be able to guarantee that it hasn't been fiddled with along the way. And if you put digitally signed provenance tracked documents under the control of the consumer and the consumer decides in turn to share them with his or her providers, they can trust those documents and understand that this is validated to act on in providing care. I really like all the dots along the way. We just need to, over the course of the summer, draw the connecting lines and we'll be there.

Paul Egerman – Software Entrepreneur
I'll just respond to the first part of what you said, David, which is indeed as you read the PCAST Report there was a lot of emphasis on patient engagement and a lot of discussion about PHR. What we were hoping to do was to leverage that as a way to get started, by saying, okay, fine, let's give patients the data. Let's let patients put it in PHRs if they want to, and also partially to speak to Walter's comment about testing things, let's see if through the process of the EHR vendor or somebody wants to step forward and start creating their own DEAS. If you read the letter there's actually one vendor who's already indicated that they are going to be doing that. So if we can get people to start doing that, that would be great because that's a way we can learn. So I think that's great. I'll let Doug answer the digital, I always call it provenance, but I guess west of the river it's a little bit different.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Is the digital signature something that was part of your discussion, Doug, when you—

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
No, but I made a note of it. I think it's a good comment.

Jonathan Perlin – Hospital Corporation of America – CMO & President
What that can do is embed a lot of the proof of authorship into an invaluable tag that goes along with the document, which is at least one subset of the provenance.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
As I think about connecting the dots and sort of this progression, direct is about sending information you know about patients you know to people you know. Eventually we want to be able to find information you want about patients you know to people you know, and then you want to be able to find the information you want about patients you know from people that you don't know. Eventually you're going to get, and when it gets into health quality and things like that it's about information you want about patients you don't know, from people you don't know, and you gradually stack those things together. And Direct solves the patients, you know, people you know, and information you know, because you sort of say, here, you're going to take care of my patient, here's some information I want you to know about that. But if you see someone in the emergency room and they've just been seen in the clinic someplace else, there's information you want, you don't have it, because no one sent it to you ahead of time, but you know the patient and you know where they were seen. I think PCAST and recommendations are along that trajectory in which you want to find information, nobody sends it to you ahead of time, you know who the patient is, but you may not know exactly where to look. So we have to be able to cover all of those bases and those are different use cases.

Janet Corrigan – National Quality Forum – President & CEO
Jon, can I get in the queue?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Yes, let's go to Dixie, Carol, Wes, and Janet.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
First, I wanted to point out that, and thank you both, you did a great job, on Doug's slide eight that this diagram of a DS is not consistent with how PCAST describes it. So I just want to make sure that people who haven't read the PCAST Report don't think that the DS actually has data elements with content metadata. The concept is that the DS would only have the metadata and would point you to the location of the data, so I think that's really an important distinction that the report made and I just wanted to make that.

Secondly, as one of our PCAST members often would point out, privacy does not equal consent, they're not synonymous, and the three elements of metadata that we identified as essential were the identity element, the provenance element, and the privacy and sensitivity, not consent. Along that line of thinking, I would expect that this table on slide nine, your slide nine, Doug, that's labeled "Consent" to have at least one data element listed that actually has something to do with patient consent, but it doesn't. All of these data elements have to do with authorization, but in fact none of them have to do with whether the patient has consented to sharing at a granular level, or even at a non-granular level. So I think that at least this assessment is not really addressing what that third metadata element needs to address, other than the one field that says "sensitivity." I know I see best without my glasses on here, but things like data type and what health plan you're covered by have nothing to do with privacy and sensitivity. I think that that part of the analysis maybe should be revisited.

Paul Egerman – Software Entrepreneur
Great comments, Dixie. As usual, you're right, what's in the metadata presentation, when they talk about "consent" it really just should say "privacy," because privacy and consent are not the same thing. There are a lot of situations where privacy tags are not consensus tags, so you're correct about privacy and you're correct about provenance. You said that there were three and you said "patient identity." Actually, the way that we looked at the report is that three were attributes, provenance, and privacy, and attributes included identity but could include some other things. So attributes could be where you might have

information about context, for example, or you might have other aspects about the data. But certainly at a minimum the attributes do have to include some patient identification material, at least for the clinician purpose of this entire process. Remember the PCAST Report does describe usage of this entire system for deidentified data which in this case the attributes presumably would have the patient identification material removed but might still have other information in it that might help you in terms of context.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Carol Diamond?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Two quick comments. Dixie actually made one of mine about the definition of the DEAS not having, the box was not corrected, does not by their description of it, have health data in it. But that makes me want to make another point, which is that the conversation about metadata in the envelope is a very different conversation from the conversation about metadata in the index. I know in a lot of the recommendations here there's a line about to create the policies that are necessary, and I would just encourage that policy conversation to happen along with a standards discussion and selection about the attributes of the metadata, because metadata can be disclosing. That's one point.

The second point actually was—and I don't think this is your intention but I think it bears punctuation. I think in the option one that you outlined in terms of the patient being able to download their own information. It's very important, and I think this bears on our deliberations here, for some of the meaningful use requirements and the general consumer access requirements, I think it's very important that the capability to download your own information comes unfettered from requirements for you to use a service or an application in order to read it. So we, I know in our work, have placed a big emphasis on the need to make sure that that download is human readable and that if it can automatically upload to a PHR that you're using, because the standards are there. Great, if you have one, but it shouldn't be a forcing function on the consumer to use one or adopt one or pay for one in order to read their own information. I think we should just be mindful of that duality that will inherently be present for a long time in this space, there's just a heterogeneity of users. Thank you.

Paul Egerman – Software Entrepreneur
Carol, great points. When we talked about downloading we did not intend that that was a replacement for an ability to view the data. It's an issue of terminology. To me when you talk about download, you're actually talking about somehow a structured machine readable form, as opposed to a patient portal where you often like to view it and print it. I don't view those as downloading, but some people call that downloading also. So it's just the terminology about what is meant by download. You clearly don't want to do what is—the patient should not be forced to receive data in a certain format. They should be able to access their information and see it, and if they want to print it they should be able to print it. But if they want to download it in some format that is structured so it could be operated on by another computer system, that should be one of their alternatives too.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I just want to clarify, I'm referring specifically in our discussions also to the requirement to fulfill the meaningful use requirement for consumer access, and I don't know that I make that exact distinction between what you call download based on the format. I just think it's important that we keep in mind that whatever the consumer uses to get that information needs to be useful to them wherever they are.

Paul Egerman – Software Entrepreneur
Excellent point.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, let's take two additional comments before we break for lunch. Wes, you're up next.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks, Jonathan. First off, I want to add to the congratulations to Paul for his handling of this. This was not as simple as herding cats. This was herding cats up a steep hill in an ice storm where a couple of

them thought they smelled a mountain lion up the hill, so that was quite a job of herding. The most important impact of the PCAST Report has been to create the opportunity for ONC to get out of the feet on the ground next stage of meaningful use focus, which has to be their bread and butter operation. They always speak of the North Star, while following the North Star with the feet on the ground, and I think this was a chance to look at the sky a little bit. I appreciate Doug's working to find ways to make that harmonize with the feet on the ground stuff as opposed to be a conflict or a fundamental choice point. It's probably the only way progress ever happens.

I think it's important to recognize that the authors brought in a fresh, non-industry specific view of all of the progress that has been made under the guise of Internet search. So I took a picture on my cell phone of a constellation at Dulles Airport and got back the name of the constellation and the ISBN number of the book that the picture came from. I was amazed. There's an awful lot of semantic searching and implied semantics being implied by the search engine, it's how they compete on relevance of search that's way beyond what all of us remember in the early days of it was just a simple match of strings that was resulting in what was hit. We know that, for example, if there's a news flash about a celebrity you're more likely to get hits on that celebrity in a Google search sooner, an ambiguous search, than you would before because they're reacting in real time that way. We know that there are already operational outside of the out of the public networking environment fairly elaborate semantic search capabilities based on healthcare semantics, and that the potential is there to support this fresh look, if you will, at the capabilities that are available. Frankly, many of the individual features or ideas in the PCAST Report are applicable in constrained environments even while policy issues are being addressed and resolved.

I happened to be talking to my colleagues at Gartner about the status of healthcare information sharing policy across a number of countries today and what I found out is that it's equally a model everywhere. That is to say, everyone can say what they want in terms of the ideal for the consumer, but it's very difficult to reduce that to practice as we ourselves have found challenging. I'd like to look particularly at the notion of the UEL. There's a stage 0 version of the UEL that was described as simply an envelope around existing blocks of data, whether those blocks of data be an image, a scanned report, a CCR, a CCD, HL-7 lab message, whatever. With the supporting metadata the functions of the DES are available and if we take the view that we saw happening already with the search engines, we could expect that the competition among DEAS' would lead to more and more ability to work with data that is structured at various levels now. Therefore, I think it's a little bit demeaning for the idea to call it stage 0, because that implies that it's a pre-production sort of level.

I think that a major jump forward either in the constrained environments where we understand the policy or when we fix the policy would be simply to get that far. There's one reading of the PCAST Report that I blog about that says that's a perfectly valid interpretation. You think of the UEL as the structure around unconstrained blogs of data. If in fact it becomes advantageous for the data sources to make it available and make it easier to find, then there's an economic incentive for them to provide more structure to those blogs rather than a constraint, which says you can't proceed with IT until you do this. There's been a lot of work going on and in production, and heavily used around detailed clinical models. I think the next step up in the UEL would be to make sure that that work is compared carefully with the constraints of the UEL.

Finally, there's an area of benefit to the UEL and the DEAS that hasn't been discussed that much, and that is to drive artificial intelligence kinds of applications, the so-called "bots" that could be serving us. I think that AI has suffered from a series of failure to meet expectations, much like people viewed PKI a few years ago. And just because PKI is becoming more widely used and more practical we shouldn't let prior experience about AI blind us to supporting that use case as we go forward. Thanks.

Paul Egerman – Software Entrepreneur

Wes, those are great observations, especially your comment about version 0 somewhat demeaning what's in the document. That is a great observation because there is a lot of utility in what was suggested there, especially when you combine that with what I called a "transport" standard, which is like the Direct Project. That combination together could create a fair amount of information exchange in a lot of environments, so that can be very useful.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, it's been a terrific discussion. Janet Corrigan, you have the final word.

Janet Corrigan – National Quality Forum – President & CEO
Oh wow, thank you. Just very quickly, first, kudos to Paul and Doug on great work; really nicely done. I just wanted to quickly connect a few more dots. HHS has been supporting the development of the quality data model for over three years now and I think the Standards Committee is going to hear a little bit about that this afternoon. I know the Clinical Quality Workgroup has been taking a close look at the QDM and that quality data model spent considerable time dealing with quite a few of the issues the PCAST slides were identified, the provenance in particular has been a major element of their work in terms of the metadata. I think there has been a good deal of groundwork and it should be possible to build on that if the Standards Committee embraces that model and shapes it going forward, it may address many of the issues that have been raised. Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific comment. Janet, the body language here really acknowledges that point. I think it's a terrific segue to this afternoon. Let me, again, thank all of the presenters on this morning, but most recently Paul Egerman and Doug Fridsma. Terrific, engaging dialogue to the committee and the participants, your first badge for endurance thinking and participation at camp, and we will gather around the bonfire of the PowerPoints at 1:45. So we'll see you back then.

Thanks, everybody for reconvening after lunch. I know there is a thunderstorm, hailstorm coming in around 4:00 this afternoon, so I think we have lost a few members who had evening commitments they couldn't miss. Jim Walker will be presenting with Karen Kmetik about the Clinical Quality Workgroup, this reinvigorated group, with a set of new work to do.

Jim, let me just introduce your remarks by saying I'd like to give your group a gift. That is that having just gone through all the meaningful use attestation and computed all the clinical quality measures for a very complex, integrated delivery network, I had my analysts keep careful notes as to how the clinical quality measures could be made easier without changing their intent. That is, they were worded in such a way that was very reasonable, and then when you get out in the field and actually have to deal with the messiness that is the healthcare data that we all collect there were certain elements of them that proved challenging. So I'll get you that list and hopefully that will inspire your future work to make the measures high quality measures, but also easy to compute.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
That's spectacular, Jon. Thank you. We are absolutely looking for that sort of thing and we'll try to incorporate it. I don't know if Karen is on. Karen? Okay, probably not. The Clinical Quality Workgroup has had two meetings now, and looking at the next slide has spectacular membership that has been a great help so far. We're looking forward to working together and the next slide.

We think our first order of business is to review the NQF's Quality Data Model with an eye to its utility and extensibility across the range of quality measures that we'll need to be implementing over the next several years, with particular attention to care coordination, capture of data from multiple sites, patient entered data, and the other new imperatives for meaningful use stage two and three. So we have been trying to stress the Quality Data Model with Floyd Eisenberg's very useful help, and so far have found that the use cases we've been able to identify, it has been able to meet as far as we're able to tell.

In our discussion, we did come up with a number of scoping considerations. This was the consensus of the workgroup that for population management, what the QDM could be responsible for is capture of person level data, which would then be aggregated in other settings. The same thing with patient safety data, that the QDM needs to be capable of capturing that person level data to be fed forward to things like the HRQ common format. Then in terms of documentation of evidence quality and documentation of population size required for measure application, we thought those were both two critically important issues to be clear about as we create the measures. But it was the consensus that both of those issues

are logically prior to implementation of quality measures in the QDM, so that those would be things that guideline developers and others would be responsible for characterizing prior to the QDM and would not need to be part of the QDM's model.

The next slide then, we thought it was also useful to try to be clear about the target audiences for the Quality Data Model. We think it will help guideline developers to understand the data needs for quality measures so that they could do a better job of creating those at the same time they create the guidelines, and similarly then for quality measure developers clearly the data model should support HIT manufacturers as they try to convert the measures into software. Then we thought that there would be some provider organizations who would have measure developers who would want to use the QDM. Partly remembering that reimbursable, meaningful use is only ever likely to be, and probably should only be a small part of the universe of the measures that organizations will need to use to assure themselves that they're providing quality and efficient care.

The next slide is we think that the next important thing we need to do is to understand as clearly as we can the kinds of things that Jon just volunteered to us. Which is what was it about MU one measures that made them useful and usable and what was it about them that could be improved so that they either are better at getting at what they're intended to get at in terms of quality, or that they're easier to implement and make effective use of. So together with the Meaningful Use Workgroup of the Policy Committee, we're planning a panel for May the 19th in which we want to hear from a large representative number of stakeholders. Their real world experiences with MU1 thus far as an input into our trying to make MU2 and MU3 more effective. If any of you have suggestions, either by the additional stakeholder groups that we should take account of, or particular panelists, obviously what we're looking for is people who will be knowledgeable, frank, and constructive to help us really figure out how to move forward effectively.

The next slide, that first bullet is back to the Quality Data Model. One of the things that Floyd's going to help us with at the next meeting is to look at the model as it would support use cases around population management. Then the bullet that's not in there is that we're trying to find out which cats we're responsible to herd and which pen we're supposed to get them into and by what date. So as we do that then we'll be looking at MU two measures first to say what are the measures that could be ready given the very tight timeline we're still up against for MU two. Then farther down the road thinking about the more substantial enhancements, more fundamental enhancements that will take a little more time and be appropriate for MU three. Jon and John, I think I'm giving you back time on the agenda. That's our report thus far.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, well we have questions. Judy Murphy?

Judy Murphy – Aurora Health Care – Vice President of Applications
Jim, are you guys, as part of your working group activity, planning on getting comments back to NQF? I know that the QDM 3 is out for public comment right now, I think until May 19th or something like that. Do you have a formal activity where you're going to actually be giving feedback to NQF on the model?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Yes. Floyd Eisenberg has joined us at all our meetings, and I think will continue to, so we're providing feedback through him.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Floyd's stepping to the table. I appreciate your volunteering to comment.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Sure, thank you. Just as feedback, the QDM just was posted for public comment, the new version today. There are actually two documents. One is the general overview and the other is a technical specification. It is open for comment. We look for comments from not only all members of this committee and the working group, but the public as well. We will incorporate all of those and then feed back to the Clinical Quality Workgroup the comments and proposed resolution that we're looking at. That's the plan.

Judy Murphy – Aurora Health Care – Vice President of Applications
I have a second comment. Jim, you mentioned that you were going to be documenting, as part of your workgroup activities what made the quality measures helpful or useful. Are you also going to document what made them very difficult in stage one?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Yes, I tried to say that, I spun it the other direction and said opportunities to improve usability and usefulness. Yes—

Judy Murphy – Aurora Health Care – Vice President of Applications
Thank you.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
... absolutely. That's the point of the panel. It's useful to hear what worked well so that we can emphasize that, but we're particularly looking for what people had trouble with. Our particular concern obviously is with smaller organizations, practices and hospitals and the particular needs that they have.

Jonathan Perlin – Hospital Corporation of America – CMO & President
As I mentioned, each of us captures data in various different ways. There are different vocabularies and some are structured and some are unstructured, and so it is a challenge for Floyd, for NQF, for you guys to come up with those that are going to be equally easy for all to compute. But I think there are some lessons learned, especially as, Jim, you so wisely stated in the past, exclusionary criteria should be optional. If your organization doesn't achieve substantial benefit from using them but a substantial burden to compute them, no problem, and those are the sorts of things that I will highlight. Floyd?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
If I can make just one other comment, we do have a list of issues we identified in doing the retooling that I will be providing to the Clinical Quality Workgroup as well, where please understand that measures that were retooled were retooled from what existed. So in some cases, for instance, it asked for blood pressure but it didn't say which one. So if there were four done during a visit and it's not asking which one, then it becomes somewhat of an implementation challenge, how do we define arrival time in a hospital compared to admission time in a standard way? You can say it in English but how do you actually specify it. There are a number of issues like that that we will be providing so that we can look for advice to this group for how to best express this.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Other questions? We had such rich discussion this morning. Everybody is just tired out or it's the postprandial somnolence or something. Okay, great. Well, Jim, success, thank you very much.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Now we'll move on to the controversial topic of the afternoon—

M
....

Jonathan Perlin – Hospital Corporation of America – CMO & President
That's it. So we'll now move on to the report from the Privacy and Security Workgroup specifically around certificate management and the provider directory activities, both entity and individual.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

The first thing I wanted to announce is that we do have a new member of our workgroup, Jeff Jonas from IBM, who was referred to me by John, and I want to thank John for referring him. He's just starting on our workgroup and I'm sure he'll make an excellent addition to our group, so thank you.

M
... is matching data and metadata even though it has been anonymized, and this is an interesting trick, which is how does one use hashing algorithms in a sophisticated fashion so that the hashes match but you don't know who you're matching.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Two things we're going to update you all on today. The first is the follow on to the digital certificate standard that we presented at the last meeting. Secondly we're going to update on our work on developing recommendations for the provider directory standard. First of all, you'll recall that at our last meeting you approved all three of our recommendations and in today's handout is a copy of the transmittal letter that was sent from this committee to the ONC with those three recommendations. We recommend specific requirements and evaluation criteria for standards for digital certificates.

The second was the recommendation that ONC investigate the benefits and alternatives of cross-certifying digital certificate authorities, direct certificate authorities, that is certificate authorities that issue digital certificates for direct exchanges with the federal bridge and I've highlighted the change that we made in that recommendation directly based on a recommendation from this committee. So we did add the explicit calling for the examination of the potential benefits of cross-certifying the federal bridge CA.

Then the third recommendation was that the Policy Committee recommend policy and governance to establish a minimum level of trustworthiness of certificate authorities that issue certificates for use in direct exchanges. So that transmittal letter has gone to the ONC. At the last meeting, we presented our preliminary work on developing requirements and evaluation criteria for a standard for provider directories. We requested that this committee give us approval to address both entity level and individual level provider directory standards at the same time, and we did get that approval so now we are proceeding addressing both needs at the same time.

However, we did run into a complication in that we anticipated that the individual level provider directory policy recommendation would be approved by the Policy Committee on April 13th, but it's been postponed to the May 11th meeting. Fortunately, we have Walter Suarez, my co-chair, who happens to be the chair of the Provider Directory Taskforce of the Information Exchange Workgroup. So what we're doing is we're proceeding with our work on the same schedule, we've made no changes, so that we can meet the immediate need for a recommendation for provider directories for stage two. We're just factoring in to our deliberations materials that we get, the publicly available materials that address the individual level provider directories. Then after the May 11th meeting of the Policy Committee, if we need to make adjustments we're prepared to do that.

At the last meeting, we told you that we had heard testimony from the VA. We had heard testimony from the NW-HIN and Direct Exchanges on their requirements for provider directories, and this last month we heard testimony from the Social Security Administration's experience developing the IHE provider directory profile and also from the X12 community, and I'll tell you a bit about what we heard from both of those. Later this month we're going to receive testimony from HL-7 on their efforts in provider directories, and we also have a speaker who has been working with the Massachusetts health information exchange who will talk about their experience. The Social Security Administration actually led the development and the conduct of a proof of concept of the Healthcare Provider Directory, or HPD profile of IHE. SSA demonstrated two use cases at this year's HIMSS Interoperability Showcase. The diagram that you see on this slide reflects the actors and the transactions that are included in that HPD profile, which includes both updating directory information and query of the directory information.

Interestingly, although the Policy Committee has separately addressed ELPDs, enterprise level and individual level provider directories, the IHE profile addresses both and accommodates both. You can use the same profile to implement both individual level or entity level provider directories. Doug, here you

see an example of Bucket C, where these are the standards that are included in the HPD profile and they include the ISO standard for health informatics, LDAP for internal queries to a provider directory, DSML for external across the Internet queries to provider directory, the SOAP for updating the information, and personnel white pages standard. All of these are existing standards and I call it Bucket C because we think we may have to tweak this set of standards, but we think it provides a good input in the whole standards that we'll be recommending to you.

The conversation with X12 was quite interesting because it really emphasized the importance that a provider directory include not only information of use for clinical exchanges, but also the importance of provider directory for administrative transactions as well. The X12 community has developed two implementation specifications, one for the provider directory and one for the provider inquiry of that directory. Both of these implementation guides include specific data, data elements that need to be included in the directory, and the X12 community has expressed a willingness to work with this committee to adjust. They're now doing the update of both of these implementation specifications and they're willing to adjust those specifications to accommodate needs that come out of this activity. So that was very encouraging to us.

The X12 is a transaction standard of course, and so it doesn't define a structure for a provider directory, and neither does the HIE profile. Both of them allow for both a centralized directory as well as for federated directory query. The observations that I thought were important to emphasize from the payer community was that the provider directory does need to maintain information regarding a provider's membership in health plans and health plans' provider networks. It's not just contact information, it needs information like the provider specialty, whether that provider's taking patients at a particular point in time, and providers' characteristics that may be useful for both consumer queries of the directory, as well as for providers' queries of the directory. All of these are included in the X12 provider directory.

The slide I'm showing now just shows the data elements that are included in the X12 provider directory transaction standards. The observations and conclusions, interestingly, all of the approaches that have been presented to our workgroup so far have looked at provider directories as a single integrated structure that contains both enterprise and individual directory information rather than a separate directory system. So they accommodate both queries for an enterprise as well as queries for an individual. Our conclusion is that the standard that we recommend needs to be implementable at both the individual and enterprise levels, as well as in a centralized or federated implementation.

Secondly, is that the provider directory standard needs to accommodate the needs of not only providers but of payers and of consumers as well. The testimony we heard from both IHE and the X12 were very, very valuable contributions to our task. So far all of the testimony that we have received have been very informative and helpful to us. We would note, finally, that the IHE healthcare provider directory profile has been demonstrated twice through two use cases at the interoperability showcase, but it's never been fully implemented in a production environment and so that's just a heads up for this committee.

Finally, our schedule, moving forward, you'll notice that actually the date there for April 27th has been changed to April 29th, you might note this on your sheet, it's from April 29th from 12:00 to 1:45, because Walter was not able to make this date and we want our chair of the taskforce to be there for sure. And you'll see in there that we will review the Implementation Workgroup's presentation materials for the ILPDs. This is the material that the Provider Directory Taskforce is working with but has not yet been approved by the Policy Committee. But by reviewing them within our workgroup we're able to stay ahead of the curve and hopefully we'll meet ONC's need for recommendations for stage two. We plan to present our recommendations for the EHR query capabilities to provider directories by next meeting. At the last meeting the ONC identified that what needs to be put in the EHR certification requirements are the query and response to and from provider directories, so we do expect to have that recommendation by the next meeting. Walter, would you like to add anything?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Just a couple of comments. The main purpose of all these activities is really the standards that will support information exchange. Interestingly enough, provider directories have now been in the big priority

list for some years until just a year ago. So there is a significant amount of activity across the industry on provider directories, and that's why the interest of making sure that the provider directories support not just the clinical exchanges, but administrative transactions and other functions, including consumer actors. So that's one point. I think the other one is the fact that by moving actually the April 27th to April 29th, on April 28th our Information Exchange Workgroup of the Policy Committee will be meeting. One of the first items is going to be finalizing the recommendations on provider directories, ILPDs, individual level, that will expected to be presented to the Policy Committee in early May. So it fits actually very nicely, because then on the 29th we will be able to start the review of that set of recommendations from the Policy Committee. So I think it's flowing very nicely.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
And to link these to what we presented at the last meeting, this provider directory is where one would go to get the digital certificate of the entity you want to exchange information with. That's why it's so important to health information exchange.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, well, I just have a comment, because Carol had to leave. Carol wanted to emphasize that as you recommend standards, and of course we've now got buckets, that you try to think about the little guy and if there are standards that have never actually been implemented in the field, those might not be appropriate for the little guy as we look forward to rapid implementation in stage two timeframes. I think this is a very fair comment, which is why you have marked this as a Bucket C kind of activity. As you said, it's widely deployed, in production, one standard; it's a work in progress.
Questions, comments? David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Just one question, Walter and Dixie, and I'm sure you covered it in the last meeting, which unfortunately I had to miss, so I should have asked the question then but I wasn't there. Is one of the core requirements, or what is the requirement around the ability to federate independent directories? Is it an assumption that the model will be a federated model of some kind, or is that up for debate as open still?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
First of all, we don't have a single requirement written down at this point. But as you saw in my last slide, slide 12, I think the standard that we recommend has to be implementable in a federated model as well as a standalone. We can't dictate the implementation.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
But federation would be something we'd shoot for?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I don't think that we would—

David McCallie – Cerner Corporation – Vice President of Medical Informatics
You wouldn't—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
... require it be federated, but the standard would have to allow for that.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
The Policy Committee recommendations, based on the hearings we had on provider directories back in September, separated from a policy perspective the entity level from the individual level. On the entity level conceptually the policy recommendations were that it will work very well if it was more of a combination of centralized with federated, meaning there will be multiple entity level provider directories, but some sort of a national directory system. But I don't think it's going to be the responsibility of the Standards Committee to define the infrastructure aspects of it. It's more our responsibility to ensure that the standards work in whatever mechanism, whether it's a more centralized or more federated or a combination of the two.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
So the use case that I have in mind is direct and at the moment direct is isolated pilots, but very quickly, starting I think with the meetings that happen later this week, we're going to try to figure out how to get the HISTs all to work together. We're using DNS as the proposed mechanism for federated discovery, if you would, of certificates. There's some degree of hope that an LDAP based solution would make sense in the long run, but it would have to be federated, because there will be hundreds of HISTs and we can't have every HIST having to update every other HIST manually out of band with every change of every address. It would be impossible. I don't see how federation can be optional in the spec.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
We did actually use this, unfortunately, you did miss on it—

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I know.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
... because we did discuss exactly that, the point that LDAP is really a protocol for within an organization. It's not Internet friendly, if you will. So we have to even though I suspect we'll include LDAP for within an enterprise, the standard has got to include some way of querying across the Internet, and that's not going to be LDAP. That will most likely be either direct or a rest type protocol.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes. There are RFCs that would let LDAP federate. There are technologies out there to do that. I don't know how widely adopted they—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
That's what DSML is. That's what the IHE, the directory services markup language, that's exactly what it does. It allows query using XML over the Internet.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I would be more interested in something that allows distributed information so that you don't have to query the network. That would be really non-scalable. Anyway, that's a technical detail to take off line.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
April 29th from 12:00 to 1:45.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Which, by the way, I just checked and you need to resend that invitation out, because it's not on the calendars.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, that was a new—

M
That was just done today.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Oh, okay. That's fine.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Other comments?

John Halamka – Harvard Medical School – Chief Information Officer
This is to the point of requirement, and I think you stated it very well. Within my organization I use LDAP for many purposes, and it works quite well. In fact, I crossed multiple entities within the Harvard

organization that are actually all in the same network, but they are multiple independent entities, and we query each other as directories using LDAP. However, as you'll hear in the testimony from the state of Massachusetts, we found that across hundreds of disparate networks with odd firewalls and unusual protocols, that LDAP wasn't very friendly. Therefore, we actually had to either use a restful or a SOAP method of querying directories in a federated and distributed manner, and yet, David, we said federated was the only possibility where we ended up doing entity level in a central location but individual in a federated fashion.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
That's very consistent with the policy recommendations of the Policy Committee.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Other comments, questions from the phone? We're looking for controversy here, but we tried them out. Okay. Were there any more digital certificate commentaries? No, I think that was it.

John Halamka – Harvard Medical School – Chief Information Officer
Really?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Yes. They had forwarded the letter and—

John Halamka – Harvard Medical School – Chief Information Officer
Terrific.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Oddly enough, we finished right on time. Let the record show that it was the new Harvard professor that finished us, I got us totally off track. With that, thank you for really robust participation, and Dixie, Walter, and other members of your workgroup, many thanks for the transmittal letter. And, let's turn back to Judy Sparrow.

Judy Sparrow – Office of the National Coordinator – Executive Director
Do we have anybody in the audience who wishes to make a comment? We've tired everybody out.

M
....

Judy Sparrow – Office of the National Coordinator – Executive Director
We do have somebody on the telephone, if you'd please identify yourself.

Robin Raiford – Allscripts – Executive Director, Federal Affairs
This is Robin Raiford from Allscripts. Thanks for the lively discussion about the happy campers and all that and who's going to lead the camp of HIT boot camp for the summer. I just wanted to bring one item to point out about the big picture and the topics today about having HIT standards participate in the NIST certifications and that sort of thing. As a consequence of something that's arising out of organizations following everything to the T having certified EHR technology, is the issue of what's happening to people with two EHRs, one in the ED, one in the hospital, and they're separate and they both have two sets of data. They both have their certified data to present for quality measures, and the issue with CMS wanting a single file per CCN, and currently the NIST criteria that don't have such a thing as certified for aggregating data. It's the all or nothing thing, which John Halamka you certainly know, since you went through that at Beth Israel Deaconess, that that is not a non-painful process to go through, to go through all of that again just to certify at the end that we need to aggregate and create one file. If that could be something that could be looked at as well, is there a way to have either aggregation on the CMS end so that the entire nation is not doing self-certification to blend these two files together because it is happening to organizations with two EHRs. Also to eligible professionals who practice in more than one location with a different EHR. It's just something to consider. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Do we have anybody else on the telephone? May I just make one announcement? Tomorrow we do in this room have a hearing on EHR usability. The Policy Committee Certification Adoption Workgroup is holding a hearing from 9:00 to 5:00 tomorrow. Then the Meaningful Use Workgroup has two hearings coming up. One is on May 3rd, which will be an in person hearing for that workgroup, and then on May 13th they're holding a specialty hearing here in Washington. I can't remember the location. Dr. Perlin?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you. Thank you for that. I hope people can attend those meetings. We obviously have a lot of work ahead of us at camp or otherwise, a number of buckets that we have to address, if you will, a punch list in each bucket, and we want to make sure that we engage in these activities in a helpful and productive way that no one kicks the bucket. So with that in mind I think if we put our heads together for a couple of next steps, John.

John Halamka – Harvard Medical School – Chief Information Officer
It's clear from today's meeting that we all want to have a clearly defined work plan so that we know what's coming up in May and June with great specificity, because they're right around the corner. And then of course getting ... in July and August, but we've got a little time before we get really specific. So as a next step, Judy, we hope to convene, Doug and Jon and I, and try to get very, very detailed about exactly what we're going to do in May and June and circulate that widely for your comments and feedback so we get that work plan.

We also, as you said, have to look at that work plan in the context of a punch list, and that is, what are the things that if we don't do them we will derail all of the fine work on meaningful use stage two and the certification rule? And I think all of us have a passion that we want to try to get our work done in a timely enough fashion that the NIST test scripts could be publicly circulated and piloted. Again, NIST did a great job and everyone worked really hard in unbelievable short time frames. But I think the number of FAQs would actually be substantially reduced if we did our work in a timely way that led to the test scripts being developed in a timely way so that they could be piloted before they went live, so we hope for that.

Also, we heard a lot of discussion about PCAST today. Doug and the MITRE folks have provided some background that now I think a group has to be assembled. Judy, I think probably with Doug you'll call for some volunteers to take a look at some of those early categories, those early lists of standards around provenance and personal identity and the privacy rather than consent, and say is this a reasonable list? Where do we take it from here? One wonders—and I hate to use the term the universal exchange language level 0, but let's just say that, we used that earlier today. Maybe level 0 actually because it's just a PHR, let's say that we're starting EHR, PHR, doesn't have yet the privacy metadata, it has the identity metadata and it has the provenance metadata because it is the person who owns the data that is exchanging it. So hence maybe we could actually come up with a relatively straightforward spec in short time that has just those two elements of metadata in it upon review of the MITRE work. I would think that those two next steps, a tight work plan for May and June and a small group ad hoc will disband after a few meetings to look at that PCAST stuff and then offer recommendations to Doug.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Thank you. I think those are excellent next steps. The other thing to think about is as we think about all the activities we have over the summer and we get the work plan together. One of the things that may be very helpful is to establish some small working groups, again, sort of ad hoc, that can help organize around solving some of those problems or addressing them specifically. These don't necessarily have to be tied to the existing set of working groups that I think will need to have. They will have other things that they'll be working on as well, but as part of that work plan we may want to identify groups that can work on those and then we can distribute the work, as I think there's so much that needs to be done. I was saying, Dixie, when she started on this committee was actually 6'4" and we have beaten her into submission because she's just done such tremendous work, and what we need, I think, is to distribute the work so that we've got lots of people who can contribute their expertise and the like as well. Otherwise, we keep turning to Dixie and all the good work she does.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Doug, and I want to thank everybody for volunteering. It's obviously a busy summer, but it's so exciting. Again, I'd reflect back to the amount of progress in the last 24 meetings, when it was going on around us that you've been so much a part of that has been very much a part of the public dialogue and we have a number of promises to make good on. Those are very complex and they're ... discussion today that we really need to work timely and have expertise broadly and look forward to working with you, Doug and the ONC team to help coordinate those activities that are on what we've been referring to as the scary list. It's a big list. It's a full list. But we can deconstruct it so that it's far less scary and much more ready and supportable for implementation with ... for not just the little guy but all who intend to do great things with healthcare.

John, do you have anything you'd like to add before—?

John Halamka – Harvard Medical School – Chief Information Officer
I'd just conclude that having now finished the attestation for meaningful use stage one, I can say that, sure there were a few items that could be polished, but on the whole it was very good. So I think we should all, based on the hard work that the Policy Committee, the Standards Committee, all of the various workgroups have done, say, we've learned a lot, I think we've actually served the country reasonably well, and I think I've used the term before, sometimes people have to eat their own dog food. This is a term of using your own work and here I've had to now both certify and attest using the work products we've created and generally, it went pretty well, so now on to stage two. Thanks, everybody and travel safely.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We are adjourned. Thank you.

Public Comment Received During the Meeting

1. I'm glad to hear the MU Workgroup is seriously considering this National Quality Strategy.

2. Really like the comments of Carol Diamond to focus on National Quality Strategy.

3. On this subject, I have not see any consideration given to the bottom line guarantee that EP's and CAH's have access to their raw data. Much of this can be guaranteed by requiring API's and data ownership requirements.

4. I presume that the text "Inspector General" is incorrect in this context, and should be Implementation Guide.

5. I'm Tom Caruso, Member of Biomedical Informatics Think Tank. I'm wondering what in the MU Stage 2 Recommendations will increase the sharing of health information. This is very important for comparative effectiveness research, other clinical research and clinical decision support systems.